

US3552010 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:06:18

All time stamps listed in this document are displayed in GMT

US3552010

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:22:22

Generated On: 10 Jun 2021 08:06:18

---

Participant ID

US3552010

---

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

---

---

US3552010

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552010

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Date of Informed Consent ( <i>dd MMM yyyy</i> )	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

US3552010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3552010

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3552010

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552010

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	ANXIETY
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)	_____

US3552010

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BILATERAL RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN SEP 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3552010

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	SEASONAL ALLERGIES
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)	_____

US3552010

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552010

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BILATERAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN APR 2017
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 APR 2017
Stop date completely unknown	False
Start Month and Year (derived)	APR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	APR 2017
Stop Year (derived)	2017

US3552010

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BILATERAL ARTHROSCOPIC KNEE SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3552010

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552010

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	TACHYCARDIA
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)	_____

US3552010

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3552010

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3552010

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	BILATERAL KNEE OSTEOARTHRITIS
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)	

US3552010

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 29 Mar 2021 13:55:31

Generated On: 10 Jun 2021 08:06:18

Condition	THYROID GOITER
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)	

US3552010

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:48
Height (xxx.x)	67 in
Weight (xxx.x)	194.2 lb
BMI (xxx.x)	30.47962 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)	

US3552010

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3552010

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2005

Date of last menstruation unknown False

US3552010

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

---

**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**

---

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

**No Risk Identified** False

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

US3552010

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

<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>	

US3552010

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 185652

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 ☒

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Height	ND - Not Done
Weight	ND - Not Done

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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)	12 AUG 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:48
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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)	12 AUG 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:52
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3552010

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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.*

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 11:22

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

US3552010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	12 AUG 2020 10:30

US3552010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	12 AUG 2020 10:35
Nasopharyngeal Swab 2	No		

US3552010

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

12 AUG 2020 11:52

PC Open Date & Time

12 AUG 2020 11:42

PC Close Date & Time

12 AUG 2020 14:12

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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 99.2 °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):

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

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

PC Time Stamp 12 AUG 2020 20:25

PC Open Date & Time 12 AUG 2020 15:07

PC Close Date & Time 13 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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 98.0 °F

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

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

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

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

PC Time Stamp 13 AUG 2020 20:18

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:17

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**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

15 AUG 2020 20:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

16 AUG 2020 20:24

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**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

18 AUG 2020 21:07

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**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

12 AUG 2020 11:55

PC Open Date & Time

12 AUG 2020 11:42

PC Close Date & Time

12 AUG 2020 14:12

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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

12 AUG 2020 20:26

PC Open Date & Time

12 AUG 2020 15:07

PC Close Date & Time

13 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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

13 AUG 2020 20:19

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**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

14 AUG 2020 20:18

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**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

15 AUG 2020 20:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**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

16 AUG 2020 20:24

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**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

17 AUG 2020 20:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**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

18 AUG 2020 21:07

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**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 ☐

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 11:57
PC Open Date & Time	12 AUG 2020 11:42
PC Close Date & Time	12 AUG 2020 14:12

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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 ☐

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 20:27
PC Open Date & Time	12 AUG 2020 15:07
PC Close Date & Time	13 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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

59 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 20:20
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

61 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:18
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

63 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:34
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

65 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:25
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

67 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:25
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

69 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:07
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3552010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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)	07 SEP 2020
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 08:37
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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)	07 SEP 2020
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 10:13
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 SEP 2020

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

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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) 07 SEP 2020

What was the treatment time? (00:00-23:59) 09:43 (24 HR)

Treatment Date and Time (derived) 07 SEP 2020 09:43

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

What was the frequency of the study treatment dosing? ONCE

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

US3552010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 SEP 2020
Collection time (00:00-23:59)	08:56 (24 HR)
Collection date and time (derived)	07 SEP 2020 08:56

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)			07 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	07 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3552010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**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

98.2 °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

07 SEP 2020 10:13

PC Open Date & Time

07 SEP 2020 10:03

PC Close Date & Time

07 SEP 2020 12:33

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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 99.5 °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	07 SEP 2020 20:55
PC Open Date & Time	07 SEP 2020 13:28
PC Close Date & Time	08 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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 100.1 °F

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

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

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

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

PC Time Stamp 08 SEP 2020 20:34

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**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

98.2 °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

09 SEP 2020 21:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**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

98.2 °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

10 SEP 2020 20:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 21:50

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**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

07 SEP 2020 10:14

PC Open Date & Time

07 SEP 2020 10:03

PC Close Date & Time

07 SEP 2020 12:33

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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

07 SEP 2020 20:56

PC Open Date & Time

07 SEP 2020 13:28

PC Close Date & Time

08 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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

08 SEP 2020 20:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**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

09 SEP 2020 21:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**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

10 SEP 2020 20:19

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**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

11 SEP 2020 21:50

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**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

13 SEP 2020 21:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**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 ☐

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 10:15
PC Open Date & Time	07 SEP 2020 10:03
PC Close Date & Time	07 SEP 2020 12:33

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**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 ☐

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 20:57
PC Open Date & Time	07 SEP 2020 13:28
PC Close Date & Time	08 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**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)

105 of 2602

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:35
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2602

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:16
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

109 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:19
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2602

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 21:51
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

113 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

115 of 2602

EAB) (1725)

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:57
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3552010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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) \_\_\_\_\_

US3552010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

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.*

US3552010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

07 OCT 2020 08:50

US3552010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:48

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

<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	14 OCT 2020 20:44:52
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 23:13:15

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 07:42:58
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 21:18:23
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 05:57:25
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

23 NOV 2020 22:27:22

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 NOV 2020 08:05:53
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 10:37:32

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

<b>TIMEPOINT</b>	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	11 DEC 2020 00:08:44
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

18 DEC 2020 06:03:41

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

27 DEC 2020 12:07:05

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 JAN 2021 09:49:08

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

08 JAN 2021 13:00:59

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 13:01:20

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

22 JAN 2021 05:49:27

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

29 JAN 2021 14:11:42

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

06 FEB 2021 07:36:11

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 00:30:39
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 11:35:47
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 FEB 2021 11:53:18

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

05 MAR 2021 13:02:51

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

14 MAR 2021 08:22:59

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 MAR 2021 22:45:07
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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

27 MAR 2021 09:35:52

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 APR 2021 14:28:31
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 17:08:42

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 10:10:38
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 13:00:57

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 13:03:44
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

20 JUL 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

30 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 AUG 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 <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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 AUG 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
---	-------------------

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 <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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 OCT 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐ Yes ☐

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59
---	-------------------

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 NOV 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

03 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

31 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 JAN 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

18 JAN 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

08 FEB 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

01 MAR 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

15 MAR 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

22 MAR 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

01 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 APR 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

[Patient Cloud Close Date & Time](#)

---

13 SEP 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 SEP 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

30 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 OCT 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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 ☐

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 OCT 2022 23:59

---

US3552010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

**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 ☐ Yes ☐

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

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3552010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:06:18

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		05 MAR 2021 13:03:04

US3552010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

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*

US3552010

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:07:05

Generated On: 10 Jun 2021 08:06:18

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

Visit date (dd MMM yyyy)	24 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	VISIT4
------------	--------

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:17:10

Generated On: 10 Jun 2021 08:06:18

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) \_\_\_\_\_

US3552010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:07:05

Generated On: 10 Jun 2021 08:06:18

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.*

US3552010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:49:12

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	08:40 (24 HR)
Collection date and time (derived)	24 FEB 2021 08:40

US3552010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:07:05

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552010

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3552010**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

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*

**US3552010**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552010

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:06:18

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"/>

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552010

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

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

Visit date (dd MMM yyyy)	12 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
------------	---------------

US3552010

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:18:57

Generated On: 10 Jun 2021 08:06:18

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3552010

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	12 JAN 2021 10:49

US3552010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	10:52
Collection Date and Time (derived)	12 JAN 2021 10:52

US3552010

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:22:23

Generated On: 10 Jun 2021 08:06:18

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

AEID	
Adverse event	L4 AND L5 NERVE COMPRESSION
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)	25 JAN 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

334 of 2602

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 JAN 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 2602

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____ _____

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

AEID	USA-US089-2021-MRNA-1273-P30 1000005
Adverse event	THYROID GOITER
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)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

338 of 2602

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

---

SUBJECT CONTACTED DUE TO  
EDIARY ENTRY FOR  
HEALTHCARE PROVIDER  
CONTACT; REPORTS THIS  
MORNING THAT SHE HAD  
SHORTNESS OF BREATH  
STARTING 3/16 WITH  
DESATURATIONS INTO THE  
80S; CONTACTED PCP WHO  
BELIEVED THIS TO BE A SIDE  
EFFECT OF MEDICATION  
(COREG). MEDICATION  
STOPPED ON 3/16, AND  
SUBJECT HAD EKG  
PERFORMED BY PCP THAT WAS  
ABNORMAL; PCP SENT  
SUBJECT TO ED. SUBJECT WAS  
ADMITTED OVERNIGHT FOR CT  
AND STRESS TEST; PER  
SUBJECT, WAS NOTED TO  
HAVE ENLARGED GOITER IN  
NECK THAT WAS  
COMPRESSING TRACHEA AND  
LUNG NODULES ON CT.  
SUBJECT SCHEDULED TO  
FOLLOW UP WITH  
PULMONOLOGY TOMORROW.  
COVID TEST IN ED WAS  
NEGATIVE. MEDICAL RECORDS  
SENT TO SPONSOR ON 3/24.  
UPDATE AS OF 05APR- SUBJECT  
HAD THYROID GOITER  
REMOVED ON 31MAR AND  
STATES THAT ALL SYMPTOMS  
HAVE RESOLVED. PLACED ON  
50MCG PO SYNTHROID DAILY.

---

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

---

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

AEID

Adverse event

RIGHT PULMONARY NODULE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

341 of 2602

EAB) (1725)

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:22:47

Generated On: 10 Jun 2021 08:06:18

---

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

Yes ☒

No ☐

---

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

---

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2013	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2005	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication DILTIAZEM ER

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 240

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)

348 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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)

350 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 AUG 2020	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication	DULOXETINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	60
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication BUPROPION ER

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 150

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)

354 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 SEP 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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

356 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2013	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication ROPINIROLE

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG SYNDROME

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)

360 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 SEP 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication CALCIUM CARBONATE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH

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 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2005	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication SUDAFED [PHENYLEPHRINE]

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

366 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH

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 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication HEALTH

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)

370 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2013	
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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication XANAX

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration .25

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN- INJECTION SITE

Dose per administration 500

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

376 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication TYLENOL

Prophylaxis Yes ☒  
No ☐

Indication OSTEOARTHRITIS

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)

378 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication IBUPROFEN

Prophylaxis Yes ☒  
No ☐

Indication OSTEOARTHRITIS

Dose per administration 400

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)

380 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

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)

382 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 400

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)

384 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify SHOT

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)

386 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)		27 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)		27 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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION, WORSENING  
HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication NERVE COMPRESSION

Dose per administration 40

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication NERVE COMPRESSION

Dose per administration 30

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

392 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)		05 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication NERVE COMPRESSION

Dose per administration 20

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	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)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication NERVE COMPRESSION

Dose per administration 10

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication AMINOPHYLLINE 250 MG/10 ML

Prophylaxis Yes ☐  
No ☒

Indication PULMONARY NODULE

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)

398 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 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)		17 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"/>

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication POST-THYROID GOITER  
REMOVAL

Dose per administration 50

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

400 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 14:26:14

Generated On: 10 Jun 2021 08:06:18

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:10:39

Generated On: 10 Jun 2021 08:06:18

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
31 MAR 2021	THYROID GOITER REMOVAL	Adverse Event	

US3552010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:06:18

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

US3552010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:06:18

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 ☐

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 11:19
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

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 08:16
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

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/APR/2021 12:01
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

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/APR/2021 09:01
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

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 16:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 17:57:33

Generated On: 10 Jun 2021 08:06:18

SAEID	USA-US089-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 06:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3552010 (Prod: Saint Louis University)

**US3552010**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:06:18**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint Verified.	(b) (4)	18 Aug 2020 21:21:14
User entered 'US3552010'	(b) (4), (b) (6)	12 Aug 2020 15:39:45
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

US3552010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
DataPoint Verified.	(b) (4)	18 Aug 2020 21:21:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:21:43
	Stanley Doublin (b) (4)	12 Aug 2020 18:34:59
	(b) (4)	

US3552010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 21:21:43
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 15:39:46

US3552010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 21:21:43
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:34:59

**US3552010**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'SCRN'	System	12 Aug 2020 18:34:59

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:39:47

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '65'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

**US3552010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:18**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'YEARS'	System	12 Aug 2020 18:35:36

**US3552010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:18**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '65'	System	12 Aug 2020 15:40:39

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

**US3552010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:18**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

**US3552010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:18**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

**US3552010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:18**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:35:36

US3552010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Aug 2020'	System	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2020'	System	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	12 Aug 2020 15:40:39

US3552010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 15:40:39

**US3552010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:18**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 15:40:39

US3552010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:39:46

US3552010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'I'	System	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:06:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:36:36

US3552010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:39:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:39:15
Data point term sent to Coder	System	12 Aug 2020 18:38:08
User entered 'hypercholesterolemia'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2013'	System	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2013'	System	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:37:38

**US3552010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:37:38

US3552010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:39:14
Data point term sent to Coder	System	12 Aug 2020 18:38:08
User entered 'hypertension'	Stanley Doublin (b) (4)	12 Aug 2020 18:38:01

US3552010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:01

US3552010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2000'	System	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2000'	System	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:01

**US3552010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:01

US3552010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
Data point term sent to Coder	System	12 Aug 2020 18:39:14
User entered 'asthma'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

US3552010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2001'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

US3552010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2001'	System	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2001'	System	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:34

**US3552010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:34

US3552010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:18
Data point term sent to Coder	System	12 Aug 2020 18:39:14
User entered 'anxiety'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

US3552010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

**US3552010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

US3552010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

US3552010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

US3552010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:38:57

**US3552010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2000'	System	12 Aug 2020 18:38:57

**US3552010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2000'	System	12 Aug 2020 18:38:57

**US3552010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:57

**US3552010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:38:57

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME (e.g. Left, Right or Bilateral Legs). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	2 Oct 2020 05:15:41
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:11:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:11:06
Data point term sent to Coder	System	29 Sep 2020 19:01:23
Query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME (e.g. Left, Right or Bilateral Legs). 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 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:15
Coding entries removed.	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:10
User entered 'bilateral RESTLESS LEG SYNDROME' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:10
User opened query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME (e.g. Left, Right or Bilateral Legs). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:33:39

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
Data point term sent to Coder	System	12 Aug 2020 18:40:15
User entered 'restless leg syndrome'	Stanley Doublin (b) (4)	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Sep 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:29

**US3552010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Sep 2017'	System	12 Aug 2020 18:39:29

**US3552010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2017'	System	12 Aug 2020 18:39:29

**US3552010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:39:29

**US3552010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:39:29

US3552010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:41:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:41:14
Data point term sent to Coder	System	12 Aug 2020 18:40:16
User entered 'seasonal allergies'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

US3552010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 1985'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

**US3552010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

US3552010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

US3552010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

US3552010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:39:55

**US3552010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 1985'	System	12 Aug 2020 18:39:55

**US3552010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '1985'	System	12 Aug 2020 18:39:55

**US3552010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:39:55

**US3552010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:39:55

US3552010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:42:20
Data point term sent to Coder	System	12 Aug 2020 18:41:19
User entered 'insomnia'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

US3552010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2014'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

US3552010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

US3552010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2014'	System	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2014'	System	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:40:27

**US3552010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:40:27

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:45:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:45:15
Data point term sent to Coder	System	12 Aug 2020 18:44:27
User entered 'bilateral knee replacement'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:43:56

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Apr 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:43:56

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:43:56

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 18:44:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 18:44:13
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	12 Aug 2020 18:44:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 18:43:56
User entered empty.	System	12 Aug 2020 18:43:56
	Stanley Dublin (b) (4)	12 Aug 2020 18:43:56
	(b) (4)	

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Apr 2017'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:43:56

US3552010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:43:56

**US3552010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Apr 2017'	System	12 Aug 2020 18:43:56

**US3552010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2017'	System	12 Aug 2020 18:43:56

**US3552010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Apr 2017'	System	12 Aug 2020 18:43:56

**US3552010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2017'	System	12 Aug 2020 18:43:56

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Per DM CLR: Please specify the laterality of ARTHROSCOPIC KNEE SURGERY (e.g. Left, Right or Bilateral Knees). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:23:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:11:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:11:08
Data point term sent to Coder	System	29 Sep 2020 19:02:28
Query 'Per DM CLR: Please specify the laterality of ARTHROSCOPIC KNEE SURGERY (e.g. Left, Right or Bilateral Knees). 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 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:57
Coding entries removed.	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:53
User entered 'bilateral ARTHROSCOPIC KNEE SURGERY' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	29 Sep 2020 19:01:53
User opened query 'Per DM CLR: Please specify the laterality of ARTHROSCOPIC KNEE SURGERY (e.g. Left, Right or Bilateral Knees). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:34:32

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:25:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:25:16
Data point term sent to Coder	System	12 Aug 2020 18:49:41
User entered 'arthroscopic knee surgery'	Stanley Doublin (b) (4)	12 Aug 2020 18:49:24

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2008'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:49:24

**US3552010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:49:24

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:49:24

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2008'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:49:24

US3552010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:49:24

**US3552010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2008'	System	12 Aug 2020 18:49:24

**US3552010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2008'	System	12 Aug 2020 18:49:24

**US3552010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2008'	System	12 Aug 2020 18:49:24

**US3552010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2008'	System	12 Aug 2020 18:49:24

US3552010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:08
Data point term sent to Coder	System	12 Aug 2020 18:50:45
User entered 'shingles'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

US3552010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Feb 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Mar 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Feb 2020'	System	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2020'	System	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Mar 2020'	System	12 Aug 2020 18:50:24

**US3552010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2020'	System	12 Aug 2020 18:50:24

US3552010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:09
Data point term sent to Coder	System	12 Aug 2020 18:51:47
User entered 'sulfa allergy'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

US3552010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 1998'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

US3552010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

US3552010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 1998'	System	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '1998'	System	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:50:54

**US3552010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:50:54

US3552010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:54:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:54:13
Data point term sent to Coder System	System	12 Aug 2020 18:52:51
User entered 'Tachycardia'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

US3552010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

US3552010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2000'	System	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2000'	System	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:51:53

**US3552010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	12 Aug 2020 18:51:53

US3552010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:58:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:58:15
Data point term sent to Coder	System	12 Aug 2020 18:57:02
User entered 'basal cell carcinoma'	Stanley Doublin (b) (4)	12 Aug 2020 18:56:18

US3552010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2001'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2001'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:56:18

US3552010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2001'	System	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2001'	System	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2001'	System	12 Aug 2020 18:56:18

**US3552010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2001'	System	12 Aug 2020 18:56:18

US3552010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Aug 2020 18:59:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:59:18
Data point term sent to Coder	System	12 Aug 2020 18:58:05
User entered 'basal cell carcinoma'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

US3552010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un Aug 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

**US3552010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

US3552010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

US3552010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	12 Aug 2020 18:57:35
User entered 'UN Aug 2019' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:57:35
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	12 Aug 2020 18:57:22
User entered 'un UNK 2019'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

US3552010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 18:57:22

**US3552010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Aug 2019'	System	12 Aug 2020 18:57:22

**US3552010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2019'	System	12 Aug 2020 18:57:22

**US3552010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Aug 2019'	System	12 Aug 2020 18:57:35
User entered 'Jan 2019'	System	12 Aug 2020 18:57:22

**US3552010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2019'	System	12 Aug 2020 18:57:22

US3552010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g. Right Knee, Bilateral Hips etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:24:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:11:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:11:08
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g. Right Knee, Bilateral Hips etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 19:02:36
Data point term sent to Coder	System	29 Sep 2020 19:02:29
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 19:02:23
User entered 'bilateral knee OSTEOARTHRITIS' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	29 Sep 2020 19:02:23
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g. Right Knee, Bilateral Hips etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:35:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:37:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:37:33
Data point term sent to Coder	System	19 Aug 2020 17:36:33
User entered 'Osteoarthritis'	Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

US3552010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

US3552010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

US3552010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '0'	Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	19 Aug 2020 17:36:12

**US3552010**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	19 Aug 2020 17:36:12

US3552010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:04:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:04:47
Data point term sent to Coder	System	04 Sep 2020 14:04:22
User entered 'Post menopausal'	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

US3552010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:06:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2005'	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

US3552010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:06:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '0'	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'Jan 2005'	System	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '2005'	System	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	04 Sep 2020 14:03:32

**US3552010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	04 Sep 2020 14:03:32

US3552010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Goiter - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	24 Mar 2021 21:23:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:23:41
	(b) (4)	
Data point term sent to Coder System	System	24 Mar 2021 21:23:13
User entered 'thyroid goiter'	Cassandra Zehenny (b) (4)	24 Mar 2021 21:22:59
	(b) (4)	

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:31
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:55:31
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	24 Mar 2021 21:22:59

**US3552010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered empty.	System	24 Mar 2021 21:22:59

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '09:48'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered '12 Aug 2020 09:48'	System	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '67' in	(b) (4) Stanley Dublin (b) (4)	12 Aug 2020 19:00:22
DataPoint set to visible.	(b) (4) System	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '194.2' lb	(b) (4) Stanley Dublin (b) (4)	12 Aug 2020 19:00:22
DataPoint set to visible.	(b) (4) System	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
Amendment Manager: User entered '30.47962'	System	16 Sep 2020 23:53:33
User entered '30.5'	System	12 Aug 2020 19:00:22
DataPoint set to visible.	System	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'kg/m2'	System	12 Aug 2020 19:00:22
DataPoint set to visible.	System	12 Aug 2020 15:41:00

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 02:37:02
Query 'Data is required. Please provide.' answered with 'temp not done' (Site from System).	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 20:40:23
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:00:22
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'bpm'	System	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'breaths/min'	System	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'mmHg'	System	12 Aug 2020 19:00:22

US3552010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:00:22

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User entered 'mmHg'	System	12 Aug 2020 19:00:22

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19

**US3552010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19

US3552010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:01:31

US3552010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 10:23:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 15:59:45
User entered '12 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:01:31

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 19:02:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:02:18
User entered '12 Aug 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	12 Aug 2020 19:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:02:09
User entered empty.	Stanley Dublin (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 05:39:38
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	04 Sep 2020 14:03:37
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 08:07:32
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'un UNK 2005'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:06:18

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:02:09

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '0'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:03:50

US3552010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:03

US3552010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:03

US3552010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[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 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'VISIT1'	System	12 Aug 2020 19:04:03

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:39:51

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:52:34
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:52:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 15:39:51
User entered '185652' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:39:51

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:39:51

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:27

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:27

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:27

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Sep 2020 18:29:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Sep 2020 18:29:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:04:27

US3552010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:04:27

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:06:18**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 16:54:42
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:46:32

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:23:40
User entered '67' in	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 16:32:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:23:40
User entered '194.2' lb	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:23:40
User entered '67' in	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Doublin (b) (4) (b) (4)	13 Aug 2020 16:32:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:23:40
User entered '194.2' lb	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:06:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:05:03
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 19:10:16
User entered '09:48' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:10:16
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 19:06:26
User entered '11:52' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '12 Aug 2020 09:48'	System	12 Aug 2020 19:10:16
User entered '12 Aug 2020 11:52'	System	12 Aug 2020 19:06:26
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '98.0' F reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:10:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 19:09:01
User entered '97.6' F reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:09:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 19:06:26
User entered '97.6' (non-conformant).	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '73' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:10:16
User entered '76' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'bpm'	System	12 Aug 2020 19:06:26
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '18' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'breaths/min'	System	12 Aug 2020 19:06:26
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '143' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:10:16
User entered '126' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	12 Aug 2020 19:06:26
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '86' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:10:16
User entered '067' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:06:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	12 Aug 2020 19:06:26
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Joan Siegner (b) (4)	12 Aug 2020 21:23:40
User entered '67' in	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 16:32:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:23:40
User entered '194.2' lb	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	12 Aug 2020 21:25:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	12 Aug 2020 21:24:53
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:07:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:07:34
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:07:34
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:05:03
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 05:51:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'data is correct' (Site from System).	Joan Siegner (b) (4)	12 Aug 2020 21:25:58
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 21:25:47
User entered '11:52' reason for change: Data Entry Error	Joan Siegner (b) (4)	12 Aug 2020 21:24:53
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '12 Aug 2020 11:52'	System	12 Aug 2020 21:25:47
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '97.6' F reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:24:53
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '76' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'bpm'	System	12 Aug 2020 21:25:47
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '18' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'breaths/min'	System	12 Aug 2020 21:25:47
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '126' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	12 Aug 2020 21:25:47
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '67' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	12 Aug 2020 21:25:47
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:05:03

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	12 Aug 2020 21:25:47
User entered empty.	System	12 Aug 2020 19:05:03

US3552010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:03:04

US3552010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:03:04

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '11:22'	(b) (4), (b) (6)	12 Aug 2020 16:50:46

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '12 Aug 2020 11:22'	System	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'ONCE'	System	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 16:50:46

US3552010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:27

US3552010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:27

US3552010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '10:30'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:27

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '12 Aug 2020 10:30'	System	12 Aug 2020 19:11:27

US3552010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:48

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:11:48

US3552010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:48

US3552010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '10:35'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:48

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '12 Aug 2020 10:35'	System	12 Aug 2020 19:11:48

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:52

US3552010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:52

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:11:52

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	12 Aug 2020 19:11:52

US3552010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Aug 2020 16:41:44

**US3552010**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'I'	System	19 Aug 2020 16:41:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:52:18', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dd0775c9-3fe0-4903-8b52-3b10c6bec681' User entered 'Yes (Y)'	System	12 Aug 2020 16:52:50
	System	12 Aug 2020 16:52:50

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:52:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dd0775c9-3fe0-4903-8b52-3b10c6bec681' User entered '97.6'	System	12 Aug 2020 16:52:50
	System	12 Aug 2020 16:52:50

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:52:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dd0775c9-3fe0-4903-8b52-3b10c6bec681' User entered 'No (N)'	System	12 Aug 2020 16:52:50
	System	12 Aug 2020 16:52:50

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:52:47', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dd0775c9-3fe0-4903-8b52-3b10c6bec681' User entered '12 Aug 2020 11:52'	System	12 Aug 2020 16:52:50
	System	12 Aug 2020 16:52:50

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 11:42'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 14:12'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167' User entered 'Yes (Y)'	System	13 Aug 2020 01:25:44
	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167' User entered '99.2'	System	13 Aug 2020 01:25:44
	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167'	System	13 Aug 2020 01:25:44
User entered 'Yes (Y)'	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Called patient, confirmed that Tylenol was given. Added to con meds and noted in source document.' (Site from System).	(b) (4)	14 Aug 2020 07:27:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Douds (b) (4)	13 Aug 2020 21:44:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:23', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167'	System	13 Aug 2020 01:25:44
User entered '1'	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:23', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167'	System	13 Aug 2020 01:25:44
User entered '0'	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:42', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c7fc1097-099e-4b53-a8e6-fc3f3e4f3167'	System	13 Aug 2020 01:25:44
User entered '12 Aug 2020 20:25'	System	13 Aug 2020 01:25:44

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 15:07'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 2'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:17:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7'	System	14 Aug 2020 01:18:34
User entered 'Yes (Y)'	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7' User entered '98.0'	System	14 Aug 2020 01:18:34
	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7'	System	14 Aug 2020 01:18:34
User entered 'Yes (Y)'	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User closed query 'Per CDM: Please confirm what medication was taken for pain or fever (Day 2 13 Aug 2020) as this is not present in the concomitant and medication page.' (Site from DM).		20 Aug 2020 11:19:11
Query 'Per CDM: Please confirm what medication was taken for pain or fever (Day 2 13 Aug 2020) as this is not present in the concomitant and medication page.' answered with 'Subject took Tylenol again on 13AUG2020, updated con meds to reflect medication from 12-13 of Aug2020' (Site from DM).	Heather Douds (b) (4)	18 Aug 2020 14:33:57
User opened query 'Per CDM: Please confirm what medication was taken for pain or fever (Day 2 13 Aug 2020) as this is not present in the concomitant and medication page.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 22:38:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		17 Aug 2020 22:34:34
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt contacted; conmed confirmed' (Site from System).	Joan Siegner (b) (4)	14 Aug 2020 13:12:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 01:18:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7'	System	14 Aug 2020 01:18:34
User entered '1'	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7' User entered '0'	System	14 Aug 2020 01:18:34
	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e07f0c1-5a60-47fe-80c8-e54f9f30d4a7'	System	14 Aug 2020 01:18:34
User entered '13 Aug 2020 20:18'	System	14 Aug 2020 01:18:34

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 3'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:09', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '9af523de-19c8-4ad5-8d52-be71b83e4d64' User entered 'Yes (Y)'	System	15 Aug 2020 01:17:29
	System	15 Aug 2020 01:17:29

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:17', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '9af523de-19c8-4ad5-8d52-be71b83e4d64' User entered '97.1'	System	15 Aug 2020 01:17:29
	System	15 Aug 2020 01:17:29

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:21', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '9af523de-19c8-4ad5-8d52-be71b83e4d64'	System	15 Aug 2020 01:17:29
User entered 'No (N)'	System	15 Aug 2020 01:17:29

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '9af523de-19c8-4ad5-8d52-be71b83e4d64' User entered '14 Aug 2020 20:17'	System	15 Aug 2020 01:17:29
	System	15 Aug 2020 01:17:29

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 4'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:32:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd4f0a1cd-3cde-4a45-99b4-67881ca107a4' User entered 'Yes (Y)'	System	16 Aug 2020 01:33:10
	System	16 Aug 2020 01:33:10

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:32:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd4f0a1cd-3cde-4a45-99b4-67881ca107a4' User entered '98.3'	System	16 Aug 2020 01:33:10
	System	16 Aug 2020 01:33:10

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:02', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd4f0a1cd-3cde-4a45-99b4-67881ca107a4'	System	16 Aug 2020 01:33:10
User entered 'No (N)'	System	16 Aug 2020 01:33:10

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:09', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd4f0a1cd-3cde-4a45-99b4-67881ca107a4' User entered '15 Aug 2020 20:33'	System	16 Aug 2020 01:33:10
	System	16 Aug 2020 01:33:10

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 5'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:23:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '904c6c89-ecff-49b3-93cf-0acd594208d4'	System	17 Aug 2020 01:24:09
User entered 'Yes (Y)'	System	17 Aug 2020 01:24:09

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:23:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '904c6c89-ecff-49b3-93cf-0acd594208d4' User entered '97.7'	System	17 Aug 2020 01:24:09
	System	17 Aug 2020 01:24:09

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:23:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '904c6c89-ecff-49b3-93cf-0acd594208d4'	System	17 Aug 2020 01:24:09
User entered 'No (N)'	System	17 Aug 2020 01:24:09

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '904c6c89-ecff-49b3-93cf-0acd594208d4' User entered '16 Aug 2020 20:24'	System	17 Aug 2020 01:24:09
	System	17 Aug 2020 01:24:09

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 6'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:23:51', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ce91048f-2b61-44b9-b1f0-007876352e6c' User entered 'Yes (Y)'	System	18 Aug 2020 01:24:18
	System	18 Aug 2020 01:24:18

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ce91048f-2b61-44b9-b1f0-007876352e6c' User entered '97.3'	System	18 Aug 2020 01:24:18
	System	18 Aug 2020 01:24:18

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ce91048f-2b61-44b9-b1f0-007876352e6c' User entered 'No (N)'	System	18 Aug 2020 01:24:18
	System	18 Aug 2020 01:24:18

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:12', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ce91048f-2b61-44b9-b1f0-007876352e6c' User entered '17 Aug 2020 20:24'	System	18 Aug 2020 01:24:18
	System	18 Aug 2020 01:24:18

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 7'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:06:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dfa39cf2-b0e7-4fe6-aca6-90a740144ed1' User entered 'Yes (Y)'	System	19 Aug 2020 02:07:14
	System	19 Aug 2020 02:07:14

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dfa39cf2-b0e7-4fe6-aca6-90a740144ed1' User entered '98.5'	System	19 Aug 2020 02:07:14
	System	19 Aug 2020 02:07:14

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:07', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dfa39cf2-b0e7-4fe6-aca6-90a740144ed1' User entered 'No (N)'	System	19 Aug 2020 02:07:14
	System	19 Aug 2020 02:07:14

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'dfa39cf2-b0e7-4fe6-aca6-90a740144ed1' User entered '18 Aug 2020 21:07'	System	19 Aug 2020 02:07:14
	System	19 Aug 2020 02:07:14

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:54:59', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '42cf409b-de56-4349-9b08-9e300f30c4a5'	System	12 Aug 2020 16:55:36
User entered 'None (1)'	System	12 Aug 2020 16:55:36

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:55:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '42cf409b-de56-4349-9b08-9e300f30c4a5'	System	12 Aug 2020 16:55:36
User entered 'No (N)'	System	12 Aug 2020 16:55:36

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:55:16', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '42cf409b-de56-4349-9b08-9e300f30c4a5'	System	12 Aug 2020 16:55:36
User entered 'No (N)'	System	12 Aug 2020 16:55:36

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:55:24', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '42cf409b-de56-4349-9b08-9e300f30c4a5'	System	12 Aug 2020 16:55:36
User entered 'None (1)'	System	12 Aug 2020 16:55:36

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:55:32', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '42cf409b-de56-4349-9b08-9e300f30c4a5' User entered '12 Aug 2020 11:55'	System	12 Aug 2020 16:55:36
	System	12 Aug 2020 16:55:36

**US3552010**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 11:42'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 14:12'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:25:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd337172e-716d-4a09-b99a-a89f59a48f82'	System	13 Aug 2020 01:26:40
User entered 'None (1)'	System	13 Aug 2020 01:26:40

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd337172e-716d-4a09-b99a-a89f59a48f82'	System	13 Aug 2020 01:26:40
User entered 'No (N)'	System	13 Aug 2020 01:26:40

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd337172e-716d-4a09-b99a-a89f59a48f82' User entered 'No (N)'	System	13 Aug 2020 01:26:40
	System	13 Aug 2020 01:26:40

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd337172e-716d-4a09-b99a-a89f59a48f82'	System	13 Aug 2020 01:26:40
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 01:26:40

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd337172e-716d-4a09-b99a-a89f59a48f82'	System	13 Aug 2020 01:26:40
User entered '12 Aug 2020 20:26'	System	13 Aug 2020 01:26:40

**US3552010**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 15:07'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 2'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:45', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f2af01aa-aeca-4368-967a-5792f5812053'	System	14 Aug 2020 01:19:15
User entered 'None (1)'	System	14 Aug 2020 01:19:15

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f2af01aa-aeca-4368-967a-5792f5812053' User entered 'No (N)'	System	14 Aug 2020 01:19:15
	System	14 Aug 2020 01:19:15

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:18:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f2af01aa-aeca-4368-967a-5792f5812053' User entered 'No (N)'	System	14 Aug 2020 01:19:15
	System	14 Aug 2020 01:19:15

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f2af01aa-aeca-4368-967a-5792f5812053'	System	14 Aug 2020 01:19:15
User entered 'None (1)'	System	14 Aug 2020 01:19:15

**US3552010**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:12', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f2af01aa-aeca-4368-967a-5792f5812053' User entered '13 Aug 2020 20:19'	System	14 Aug 2020 01:19:15
	System	14 Aug 2020 01:19:15

**US3552010**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 3'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:51', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '32f3ccd2-cfe6-4e35-b0a3-9d55b5dca20e'	System	15 Aug 2020 01:18:17
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:18:17

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:55', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '32f3ccd2-cfe6-4e35-b0a3-9d55b5dca20e' User entered 'No (N)'	System	15 Aug 2020 01:18:17
	System	15 Aug 2020 01:18:17

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:17:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '32f3ccd2-cfe6-4e35-b0a3-9d55b5dca20e' User entered 'No (N)'	System	15 Aug 2020 01:18:17
	System	15 Aug 2020 01:18:17

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '32f3ccd2-cfe6-4e35-b0a3-9d55b5dca20e' User entered 'None (1)'	System	15 Aug 2020 01:18:17
	System	15 Aug 2020 01:18:17

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:14', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '32f3ccd2-cfe6-4e35-b0a3-9d55b5dca20e' User entered '14 Aug 2020 20:18'	System	15 Aug 2020 01:18:17
	System	15 Aug 2020 01:18:17

**US3552010**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 4'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '510b1239-c2f9-4a54-baf6-66e6e1d437b2'	System	16 Aug 2020 01:33:37
User entered 'None (1)'	System	16 Aug 2020 01:33:37

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:22', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '510b1239-c2f9-4a54-baf6-66e6e1d437b2'	System	16 Aug 2020 01:33:37
User entered 'No (N)'	System	16 Aug 2020 01:33:37

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '510b1239-c2f9-4a54-baf6-66e6e1d437b2'	System	16 Aug 2020 01:33:37
User entered 'No (N)'	System	16 Aug 2020 01:33:37

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:30', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '510b1239-c2f9-4a54-baf6-66e6e1d437b2'	System	16 Aug 2020 01:33:37
User entered 'None (1)'	System	16 Aug 2020 01:33:37

**US3552010**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '510b1239-c2f9-4a54-baf6-66e6e1d437b2' User entered '15 Aug 2020 20:33'	System	16 Aug 2020 01:33:37
	System	16 Aug 2020 01:33:37

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 5'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:13', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c9c882a-c239-4c81-a60f-1705d1d22a51'	System	17 Aug 2020 01:24:49
User entered 'None (1)'	System	17 Aug 2020 01:24:49

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:16', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c9c882a-c239-4c81-a60f-1705d1d22a51' User entered 'No (N)'	System	17 Aug 2020 01:24:49
	System	17 Aug 2020 01:24:49

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c9c882a-c239-4c81-a60f-1705d1d22a51' User entered 'No (N)'	System	17 Aug 2020 01:24:49
	System	17 Aug 2020 01:24:49

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:36', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c9c882a-c239-4c81-a60f-1705d1d22a51'	System	17 Aug 2020 01:24:49
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 01:24:49

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c9c882a-c239-4c81-a60f-1705d1d22a51' User entered '16 Aug 2020 20:24'	System	17 Aug 2020 01:24:49
	System	17 Aug 2020 01:24:49

**US3552010**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 6'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd3b7f8d8-9346-4be2-9276-398768ef4e49'	System	18 Aug 2020 01:24:46
User entered 'None (1)'	System	18 Aug 2020 01:24:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:23', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd3b7f8d8-9346-4be2-9276-398768ef4e49'	System	18 Aug 2020 01:24:46
User entered 'No (N)'	System	18 Aug 2020 01:24:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:28', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd3b7f8d8-9346-4be2-9276-398768ef4e49' User entered 'No (N)'	System	18 Aug 2020 01:24:46
	System	18 Aug 2020 01:24:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd3b7f8d8-9346-4be2-9276-398768ef4e49'	System	18 Aug 2020 01:24:46
User entered 'None (1)'	System	18 Aug 2020 01:24:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:45', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd3b7f8d8-9346-4be2-9276-398768ef4e49' User entered '17 Aug 2020 20:24'	System	18 Aug 2020 01:24:46
	System	18 Aug 2020 01:24:46

**US3552010**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 7'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:16', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b24516db-10ab-4469-8444-d8d18bd66c70'	System	19 Aug 2020 02:07:33
User entered 'None (1)'	System	19 Aug 2020 02:07:33

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b24516db-10ab-4469-8444-d8d18bd66c70' User entered 'No (N)'	System	19 Aug 2020 02:07:33
	System	19 Aug 2020 02:07:33

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:22', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b24516db-10ab-4469-8444-d8d18bd66c70' User entered 'No (N)'	System	19 Aug 2020 02:07:33
	System	19 Aug 2020 02:07:33

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b24516db-10ab-4469-8444-d8d18bd66c70'	System	19 Aug 2020 02:07:33
User entered 'None (1)'	System	19 Aug 2020 02:07:33

US3552010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b24516db-10ab-4469-8444-d8d18bd66c70' User entered '18 Aug 2020 21:07'	System	19 Aug 2020 02:07:33
	System	19 Aug 2020 02:07:33

**US3552010**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:42', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

**US3552010**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:56:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered 'None (0)'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:57:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c'	System	12 Aug 2020 16:57:16
User entered 'No (N)'	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T11:57:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3775ab87-9df8-48bb-aa69-7dbf49d60f2c' User entered '12 Aug 2020 11:57'	System	12 Aug 2020 16:57:16
	System	12 Aug 2020 16:57:16

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 11:42'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 14:12'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:45', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'No interference with activity (1)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:51', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'Some interference with activity (2)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:26:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'Some interference with activity (2)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:27:02', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'Some interference with activity (2)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:27:17', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:27:24', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e' User entered 'None (0)'	System	13 Aug 2020 01:27:42
	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:27:30', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered 'No (N)'	System	13 Aug 2020 01:27:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-12T20:27:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fe597f7-7118-4e81-a9ee-48387e020c5e'	System	13 Aug 2020 01:27:42
User entered '12 Aug 2020 20:27'	System	13 Aug 2020 01:27:42

**US3552010**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Aug 2020 15:07'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 2'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:18', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered 'None (0)'	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:24', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered 'Some interference with activity (2)'	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:30', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered 'Some interference with activity (2)'	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered 'Some interference with activity (2)'	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32' User entered 'None (0)'	System	14 Aug 2020 01:20:11
	System	14 Aug 2020 01:20:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32' User entered 'None (0)'	System	14 Aug 2020 01:20:11
	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:19:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered 'No (N)'	System	14 Aug 2020 01:20:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-13T20:20:09', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '88bcf7a7-9ef9-4144-a8e5-cffd854beb32'	System	14 Aug 2020 01:20:11
User entered '13 Aug 2020 20:20'	System	14 Aug 2020 01:20:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 3'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:27', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:31', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:37', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'None (0)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered 'No (N)'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-14T20:18:55', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6cf9c6b7-3f10-4cad-b147-994577a3d395' User entered '14 Aug 2020 20:18'	System	15 Aug 2020 01:18:59
	System	15 Aug 2020 01:18:59

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 4'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:47', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:51', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:54', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:33:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:34:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered 'None (0)'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:34:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5'	System	16 Aug 2020 01:34:11
User entered 'No (N)'	System	16 Aug 2020 01:34:11

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-15T20:34:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '82e53ad4-74e9-44f2-ba51-b6cc8f51d4c5' User entered '15 Aug 2020 20:34'	System	16 Aug 2020 01:34:11
	System	16 Aug 2020 01:34:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 5'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:52', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered 'None (0)'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:24:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3'	System	17 Aug 2020 01:25:42
User entered 'No interference with activity (1)'	System	17 Aug 2020 01:25:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered 'None (0)'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered 'None (0)'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered 'None (0)'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered 'None (0)'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:31', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3'	System	17 Aug 2020 01:25:42
User entered 'No (N)'	System	17 Aug 2020 01:25:42

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-16T20:25:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '31f863b0-aa73-4a1a-9874-fd944f91a7e3' User entered '16 Aug 2020 20:25'	System	17 Aug 2020 01:25:42
	System	17 Aug 2020 01:25:42

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 6'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:24:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:02', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'None (0)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:14', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered 'No (N)'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-17T20:25:17', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4cc6bb02-1f4b-4768-9156-2fb1b7fc2eb0' User entered '17 Aug 2020 20:25'	System	18 Aug 2020 01:25:19
	System	18 Aug 2020 01:25:19

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 7'	System	12 Aug 2020 16:50:46

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:36', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:43', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered 'None (0)'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:52', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c'	System	19 Aug 2020 02:07:57
User entered 'No (N)'	System	19 Aug 2020 02:07:57

US3552010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-08-18T21:07:55', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f7dc0c30-42e2-44b9-a862-f6acd604c42c' User entered '18 Aug 2020 21:07'	System	19 Aug 2020 02:07:57
	System	19 Aug 2020 02:07:57

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:50:46

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:50:46

US3552010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Aug 2020 16:42:02

US3552010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '19 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Aug 2020 16:42:02

US3552010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Aug 2020 16:42:02

US3552010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Aug 2020 16:42:02

US3552010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Joan Siegner (b) (4)	26 Aug 2020 17:54:48

**US3552010**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	26 Aug 2020 17:54:48

**US3552010**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Joan Siegner (b) (4)	26 Aug 2020 17:56:03

**US3552010**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '26 Aug 2020'	(b) (4) Joan Siegner (b) (4)	26 Aug 2020 17:56:03

**US3552010**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	26 Aug 2020 17:56:03

US3552010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Joan Siegner (b) (4)	26 Aug 2020 17:56:03

US3552010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Joan Siegner (b) (4)	02 Sep 2020 16:49:12

**US3552010**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'I'	System	02 Sep 2020 16:49:12

**US3552010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Joan Siegner (b) (4)	02 Sep 2020 16:49:36

US3552010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '02 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:09:42
User entered '2 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	02 Sep 2020 16:49:36

**US3552010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	02 Sep 2020 16:49:36

US3552010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Joan Siegner (b) (4) [REDACTED]	02 Sep 2020 16:49:36

US3552010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:09:02

**US3552010**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	07 Sep 2020 14:09:02

US3552010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 15:59:45

US3552010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	09 Nov 2020 14:09:51
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 05:54:21
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Data correct as entered, in appropriate window per visit calculator' (Site from System).	Heather Douds (b) (4) (b) (4)	07 Sep 2020 16:13:08
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Sep 2020 15:59:45
User entered '7 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 15:59:45

US3552010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 15:59:45

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'VISIT2'	System	07 Sep 2020 15:59:45

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:01
User entered '7 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '08:37'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Sep 2020 08:37'	System	09 Nov 2020 14:10:01
User entered '7 Sep 2020 08:37'	System	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '98.9' F	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '80'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'bpm'	System	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'breaths/min'	System	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '143'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '73'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	07 Sep 2020 16:02:12

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:01
User entered '7 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '10:13'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Sep 2020 10:13'	System	09 Nov 2020 14:10:01
User entered '7 Sep 2020 10:13'	System	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '98.2' F	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '81'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'bpm'	System	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '16'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'breaths/min'	System	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '145'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '80'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'mmHg'	System	07 Sep 2020 16:02:46

US3552010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:54

US3552010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:08
User entered '7 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:02:54

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:18
User entered '7 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '09:43'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:47:28

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Sep 2020 09:43'	System	09 Nov 2020 14:10:18
User entered '7 Sep 2020 09:43'	System	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'ONCE'	System	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 14:47:28

US3552010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:16

US3552010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	09 Nov 2020 14:10:25
User entered '7 Sep 2020'	(b) (4)	
	Stanley Dublin (b) (4)	07 Sep 2020 16:03:16
	(b) (4)	

US3552010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '08:56'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:16

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Sep 2020 08:56'	System	09 Nov 2020 14:10:25
User entered '7 Sep 2020 08:56'	System	07 Sep 2020 16:03:16

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:33
User entered '7 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '09:00'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Sep 2020 09:00'	System	09 Nov 2020 14:10:33
User entered '7 Sep 2020 09:00'	System	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Sep 2020 16:03:30

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Sep 2020 16:03:30

US3552010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Sep 2020 16:04:52

**US3552010**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'I'	System	14 Sep 2020 16:04:52

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:13:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7a8505d6-240d-48bf-901b-c06c7c94a71f' User entered 'Yes (Y)'	System	07 Sep 2020 15:13:51
	System	07 Sep 2020 15:13:51

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:13:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7a8505d6-240d-48bf-901b-c06c7c94a71f' User entered '98.2'	System	07 Sep 2020 15:13:51
	System	07 Sep 2020 15:13:51

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:13:37', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7a8505d6-240d-48bf-901b-c06c7c94a71f' User entered 'No (N)'	System	07 Sep 2020 15:13:51
	System	07 Sep 2020 15:13:51

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:13:48', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7a8505d6-240d-48bf-901b-c06c7c94a71f' User entered '07 Sep 2020 10:13'	System	07 Sep 2020 15:13:51
	System	07 Sep 2020 15:13:51

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 10:03'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:54:59', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fe52a060-9a07-4b62-a41b-5bb4565dd0c5' User entered 'Yes (Y)'	System	08 Sep 2020 01:55:23
	System	08 Sep 2020 01:55:23

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:55:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fe52a060-9a07-4b62-a41b-5bb4565dd0c5' User entered '99.5'	System	08 Sep 2020 01:55:23
	System	08 Sep 2020 01:55:23

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:55:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fe52a060-9a07-4b62-a41b-5bb4565dd0c5' User entered 'No (N)'	System	08 Sep 2020 01:55:23
	System	08 Sep 2020 01:55:23

**US3552010**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:55:21', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fe52a060-9a07-4b62-a41b-5bb4565dd0c5' User entered '07 Sep 2020 20:55'	System	08 Sep 2020 01:55:23
	System	08 Sep 2020 01:55:23

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 13:28'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 2'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:33:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3' User entered 'Yes (Y)'	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:33:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3' User entered '100.1'	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:33:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3'	System	09 Sep 2020 01:34:03
User entered 'Yes (Y)'	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Took tylenol and ibuprofen for injection site pain, con meds updated' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 04:00:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:33:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3' User entered 'I'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 15:18:20
	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:33:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3' User entered '0'	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:34:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '25fdc8b2-591d-4bc5-9d44-7f67888090d3' User entered '08 Sep 2020 20:34'	System	09 Sep 2020 01:34:03
	System	09 Sep 2020 01:34:03

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 3'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:14:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7c305d37-b57e-4a06-af1b-7874e3af803e' User entered 'Yes (Y)'	System	10 Sep 2020 02:14:46
	System	10 Sep 2020 02:14:46

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:14:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7c305d37-b57e-4a06-af1b-7874e3af803e' User entered '98.2'	System	10 Sep 2020 02:14:46
	System	10 Sep 2020 02:14:46

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:14:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7c305d37-b57e-4a06-af1b-7874e3af803e' User entered 'No (N)'	System	10 Sep 2020 02:14:46
	System	10 Sep 2020 02:14:46

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:14:43', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7c305d37-b57e-4a06-af1b-7874e3af803e' User entered '09 Sep 2020 21:14'	System	10 Sep 2020 02:14:46
	System	10 Sep 2020 02:14:46

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 4'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:18:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '98971036-d558-471e-82a9-1975f8f21f0d' User entered 'Yes (Y)'	System	11 Sep 2020 01:18:50
	System	11 Sep 2020 01:18:50

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:18:37', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '98971036-d558-471e-82a9-1975f8f21f0d' User entered '98.2'	System	11 Sep 2020 01:18:50
	System	11 Sep 2020 01:18:50

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:18:43', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '98971036-d558-471e-82a9-1975f8f21f0d'	System	11 Sep 2020 01:18:50
User entered 'No (N)'	System	11 Sep 2020 01:18:50

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:18:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '98971036-d558-471e-82a9-1975f8f21f0d' User entered '10 Sep 2020 20:18'	System	11 Sep 2020 01:18:50
	System	11 Sep 2020 01:18:50

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 5'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:49:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fb14ad4-b68a-4e76-9192-d6aac6d99f36' User entered 'Yes (Y)'	System	12 Sep 2020 02:50:14
	System	12 Sep 2020 02:50:14

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fb14ad4-b68a-4e76-9192-d6aac6d99f36' User entered '97.9'	System	12 Sep 2020 02:50:14
	System	12 Sep 2020 02:50:14

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fb14ad4-b68a-4e76-9192-d6aac6d99f36'	System	12 Sep 2020 02:50:14
User entered 'No (N)'	System	12 Sep 2020 02:50:14

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6fb14ad4-b68a-4e76-9192-d6aac6d99f36'	System	12 Sep 2020 02:50:14
User entered '11 Sep 2020 21:50'	System	12 Sep 2020 02:50:14

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 6'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 7'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:55:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '56ea5bfd-3fa0-4a2a-aebc-a9dfa41959a1' User entered 'Yes (Y)'	System	14 Sep 2020 02:56:25
	System	14 Sep 2020 02:56:25

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:07', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '56ea5bfd-3fa0-4a2a-aebc-a9dfa41959a1' User entered '98.0'	System	14 Sep 2020 02:56:25
	System	14 Sep 2020 02:56:25

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '56ea5bfd-3fa0-4a2a-aebc-a9dfa41959a1' User entered 'No (N)'	System	14 Sep 2020 02:56:25
	System	14 Sep 2020 02:56:25

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:22', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '56ea5bfd-3fa0-4a2a-aebc-a9dfa41959a1' User entered '13 Sep 2020 21:56'	System	14 Sep 2020 02:56:25
	System	14 Sep 2020 02:56:25

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:13:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fda0a62c-493f-4f92-94a2-a4eec957157e' User entered 'None (1)'	System	07 Sep 2020 15:14:24
	System	07 Sep 2020 15:14:24

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:07', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fda0a62c-493f-4f92-94a2-a4eec957157e' User entered 'No (N)'	System	07 Sep 2020 15:14:24
	System	07 Sep 2020 15:14:24

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fda0a62c-493f-4f92-94a2-a4eec957157e' User entered 'No (N)'	System	07 Sep 2020 15:14:24
	System	07 Sep 2020 15:14:24

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:16', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fda0a62c-493f-4f92-94a2-a4eec957157e' User entered 'None (1)'	System	07 Sep 2020 15:14:24
	System	07 Sep 2020 15:14:24

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:21', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'fda0a62c-493f-4f92-94a2-a4eec957157e' User entered '07 Sep 2020 10:14'	System	07 Sep 2020 15:14:24
	System	07 Sep 2020 15:14:24

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 10:03'	System	07 Sep 2020 14:47:28

**US3552010**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:55:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5b95caec-a18f-4d5e-9e09-6ead4f758da5'	System	08 Sep 2020 01:56:58
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		08 Sep 2020 01:56:58

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:56:09', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5b95caec-a18f-4d5e-9e09-6ead4f758da5' User entered 'No (N)'	System	08 Sep 2020 01:56:58
	System	08 Sep 2020 01:56:58

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:56:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5b95caec-a18f-4d5e-9e09-6ead4f758da5' User entered 'No (N)'	System	08 Sep 2020 01:56:58
	System	08 Sep 2020 01:56:58

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:56:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5b95caec-a18f-4d5e-9e09-6ead4f758da5' User entered 'None (1)'	System	08 Sep 2020 01:56:58
	System	08 Sep 2020 01:56:58

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:56:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5b95caec-a18f-4d5e-9e09-6ead4f758da5' User entered '07 Sep 2020 20:56'	System	08 Sep 2020 01:56:58
	System	08 Sep 2020 01:56:58

**US3552010**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 13:28'	System	07 Sep 2020 14:47:28

**US3552010**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 2'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:34:27', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd871e295-0136-4ffb-841b-e47c50da8225'	System	09 Sep 2020 01:35:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	09 Sep 2020 01:35:22

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:34:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd871e295-0136-4ffb-841b-e47c50da8225'	System	09 Sep 2020 01:35:22
User entered 'No (N)'	System	09 Sep 2020 01:35:22

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:34:51', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd871e295-0136-4ffb-841b-e47c50da8225'	System	09 Sep 2020 01:35:22
User entered 'No (N)'	System	09 Sep 2020 01:35:22

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd871e295-0136-4ffb-841b-e47c50da8225'	System	09 Sep 2020 01:35:22
User entered 'None (1)'	System	09 Sep 2020 01:35:22

**US3552010**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd871e295-0136-4ffb-841b-e47c50da8225' User entered '08 Sep 2020 20:35'	System	09 Sep 2020 01:35:22
	System	09 Sep 2020 01:35:22

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 3'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21b7c84f-c58d-4dac-8a32-baa0e2485e71'	System	10 Sep 2020 02:15:45
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		10 Sep 2020 02:15:45

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21b7c84f-c58d-4dac-8a32-baa0e2485e71' User entered 'No (N)'	System	10 Sep 2020 02:15:45
	System	10 Sep 2020 02:15:45

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:18', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21b7c84f-c58d-4dac-8a32-baa0e2485e71' User entered 'No (N)'	System	10 Sep 2020 02:15:45
	System	10 Sep 2020 02:15:45

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21b7c84f-c58d-4dac-8a32-baa0e2485e71' User entered 'None (1)'	System	10 Sep 2020 02:15:45
	System	10 Sep 2020 02:15:45

**US3552010**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:43', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21b7c84f-c58d-4dac-8a32-baa0e2485e71' User entered '09 Sep 2020 21:15'	System	10 Sep 2020 02:15:45
	System	10 Sep 2020 02:15:45

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 4'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:18:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c8976da8-49ff-4854-8a6d-d2c8245452d9'	System	11 Sep 2020 01:19:16
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:19:16

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:02', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c8976da8-49ff-4854-8a6d-d2c8245452d9' User entered 'No (N)'	System	11 Sep 2020 01:19:16
	System	11 Sep 2020 01:19:16

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c8976da8-49ff-4854-8a6d-d2c8245452d9' User entered 'No (N)'	System	11 Sep 2020 01:19:16
	System	11 Sep 2020 01:19:16

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c8976da8-49ff-4854-8a6d-d2c8245452d9' User entered 'None (1)'	System	11 Sep 2020 01:19:16
	System	11 Sep 2020 01:19:16

**US3552010**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c8976da8-49ff-4854-8a6d-d2c8245452d9' User entered '10 Sep 2020 20:19'	System	11 Sep 2020 01:19:16
	System	11 Sep 2020 01:19:16

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 5'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2a71fa95-f83b-4b18-935c-2b8fa5ebe009'	System	12 Sep 2020 02:50:40
User entered 'None (1)'	System	12 Sep 2020 02:50:40

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:24', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2a71fa95-f83b-4b18-935c-2b8fa5ebe009'	System	12 Sep 2020 02:50:40
User entered 'No (N)'	System	12 Sep 2020 02:50:40

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:28', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2a71fa95-f83b-4b18-935c-2b8fa5ebe009' User entered 'No (N)'	System	12 Sep 2020 02:50:40
	System	12 Sep 2020 02:50:40

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:32', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2a71fa95-f83b-4b18-935c-2b8fa5ebe009'	System	12 Sep 2020 02:50:40
User entered 'None (1)'	System	12 Sep 2020 02:50:40

**US3552010**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2a71fa95-f83b-4b18-935c-2b8fa5ebe009'	System	12 Sep 2020 02:50:40
User entered '11 Sep 2020 21:50'	System	12 Sep 2020 02:50:40

**US3552010**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 6'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 7'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '488a70f5-6b71-4050-b9eb-80af38228eb3'	System	14 Sep 2020 02:56:47
User entered 'None (1)'	System	14 Sep 2020 02:56:47

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:33', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '488a70f5-6b71-4050-b9eb-80af38228eb3' User entered 'No (N)'	System	14 Sep 2020 02:56:47
	System	14 Sep 2020 02:56:47

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:36', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '488a70f5-6b71-4050-b9eb-80af38228eb3' User entered 'No (N)'	System	14 Sep 2020 02:56:47
	System	14 Sep 2020 02:56:47

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:42', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '488a70f5-6b71-4050-b9eb-80af38228eb3'	System	14 Sep 2020 02:56:47
User entered 'None (1)'	System	14 Sep 2020 02:56:47

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:45', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '488a70f5-6b71-4050-b9eb-80af38228eb3'	System	14 Sep 2020 02:56:47
User entered '13 Sep 2020 21:56'	System	14 Sep 2020 02:56:47

US3552010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:33', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

**US3552010**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'None (0)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:14:47', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered 'No (N)'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T10:15:18', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '49423d96-51c6-4161-b59e-50417a3dce06' User entered '07 Sep 2020 10:15'	System	07 Sep 2020 15:15:22
	System	07 Sep 2020 15:15:22

**US3552010**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 10:03'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 12:33'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:09', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered 'No interference with activity (1)'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered 'Significant; prevents daily activity (3)'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:23', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered 'Significant; prevents daily activity (3)'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:28', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered 'Significant; prevents daily activity (3)'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:36', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb'	System	08 Sep 2020 01:57:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb'	System	08 Sep 2020 01:57:51
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:45', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered 'No (N)'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-07T20:57:48', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1553ab8c-6aa6-453e-ab1d-d43e6d15dcdb' User entered '07 Sep 2020 20:57'	System	08 Sep 2020 01:57:51
	System	08 Sep 2020 01:57:51

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '07 Sep 2020 13:28'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 2'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:27', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:36:00

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:33', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'Significant; prevents daily activity (3)'	System	09 Sep 2020 01:36:00

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:37', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'Significant; prevents daily activity (3)'	System	09 Sep 2020 01:36:00

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'Significant; prevents daily activity (3)'	System	09 Sep 2020 01:36:00

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 01:36:00

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:50', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:36:00

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:54', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered 'No (N)'	System	09 Sep 2020 01:36:00

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-08T20:35:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'd75c6ba5-10e5-4973-a8b7-5ec8a7cf6f95'	System	09 Sep 2020 01:36:00
User entered '08 Sep 2020 20:35'	System	09 Sep 2020 01:36:00

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 3'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:15:59', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:16:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:16:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'None (0)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:16:06', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered 'No (N)'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-09T21:16:10', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '0d027d7a-dc84-4073-93ac-5bcf1ce8e724' User entered '09 Sep 2020 21:16'	System	10 Sep 2020 02:16:14
	System	10 Sep 2020 02:16:14

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 4'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:22', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:26', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:28', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:31', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'None (0)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:37', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1' User entered 'No (N)'	System	11 Sep 2020 01:19:41
	System	11 Sep 2020 01:19:41

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-10T20:19:39', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '6a6c2052-b302-458a-875c-65fdebab29d1'	System	11 Sep 2020 01:19:41
User entered '10 Sep 2020 20:19'	System	11 Sep 2020 01:19:41

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 5'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:47', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:50', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:50:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:51:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'None (0)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:51:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08' User entered 'No (N)'	System	12 Sep 2020 02:51:11
	System	12 Sep 2020 02:51:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-11T21:51:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5c4ccf88-9a04-4724-b3dd-d62129a56f08'	System	12 Sep 2020 02:51:11
User entered '11 Sep 2020 21:51'	System	12 Sep 2020 02:51:11

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 6'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	07 Sep 2020 14:47:28
User entered 'Day 7'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:54', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:56:59', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:57:01', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:57:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered 'None (0)'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

US3552010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:57:14', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dc650'	System	14 Sep 2020 02:57:21
User entered 'No (N)'	System	14 Sep 2020 02:57:21

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-09-13T21:57:18', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'db4d60ac-986c-46c0-a305-be287dced650' User entered '13 Sep 2020 21:57'	System	14 Sep 2020 02:57:21
	System	14 Sep 2020 02:57:21

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 14:47:28

**US3552010**

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

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

**Generated On: 10 Jun 2021 08:06:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 14:47:28

**US3552010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Sep 2020 16:05:27

**US3552010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '14 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Sep 2020 16:05:27

US3552010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	14 Sep 2020 16:05:27

US3552010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Sep 2020 16:05:27

US3552010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 15:47:04

**US3552010**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	21 Sep 2020 15:47:04

US3552010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 15:47:13

**US3552010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 15:47:13

**US3552010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 15:47:13

US3552010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 15:47:13

US3552010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:19:09

**US3552010**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	28 Sep 2020 17:19:09

**US3552010**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:19:17

US3552010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '28 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:19:17

US3552010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:19:17

US3552010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:19:17

US3552010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:34

**US3552010**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	07 Oct 2020 17:45:34

US3552010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:43

US3552010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:10:55
User entered '7 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:43

US3552010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[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 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:43

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'VISIT3'	System	07 Oct 2020 17:45:43

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Oct 2020 17:45:49

US3552010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:45:49

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered empty.	System	07 Oct 2020 17:45:49

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

**Weight (derived)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17

US3552010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:46:00

US3552010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:46:00

US3552010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:46:13

US3552010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '07 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:11:15
User entered '7 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:46:13

US3552010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '08:50'	Stanley Dublin (b) (4) (b) (4)	07 Oct 2020 17:46:13

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered '07 Oct 2020 08:50'	System	09 Nov 2020 14:11:15
User entered '7 Oct 2020 08:50'	System	07 Oct 2020 17:46:13

US3552010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:20:58

**US3552010**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'I'	System	04 Nov 2020 16:20:58

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 64'	System	12 Aug 2020 16:50:46

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-14T20:44:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '8af57bb6-0a5e-45a5-8b07-1392188ce4cc'	System	15 Oct 2020 01:44:57
User entered 'No (N)'	System	15 Oct 2020 01:44:57

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-14T20:44:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '8af57bb6-0a5e-45a5-8b07-1392188ce4cc'	System	15 Oct 2020 01:44:57
User entered 'No (N)'	System	15 Oct 2020 01:44:57

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-14T20:44:52', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '8af57bb6-0a5e-45a5-8b07-1392188ce4cc' User entered '14 Oct 2020 20:44:52'	System	15 Oct 2020 01:44:57
	System	15 Oct 2020 01:44:57

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 71'	System	12 Aug 2020 16:50:46

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-19T23:12:57', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c51e7db4-6b82-4898-98b5-42a6993061e4'	System	20 Oct 2020 04:13:17
User entered 'No (N)'	System	20 Oct 2020 04:13:17

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-19T23:13:07', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c51e7db4-6b82-4898-98b5-42a6993061e4'	System	20 Oct 2020 04:13:17
User entered 'No (N)'	System	20 Oct 2020 04:13:17

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-19T23:13:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c51e7db4-6b82-4898-98b5-42a6993061e4' User entered '19 Oct 2020 23:13:15'	System	20 Oct 2020 04:13:17
	System	20 Oct 2020 04:13:17

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 78'	System	12 Aug 2020 16:50:46

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-26T07:42:40', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1bea1e61-ca98-4e46-bd28-69b2aa34628f' User entered 'No (N)'	System	26 Oct 2020 12:43:03
	System	26 Oct 2020 12:43:03

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-26T07:42:49', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1bea1e61-ca98-4e46-bd28-69b2aa34628f' User entered 'No (N)'	System	26 Oct 2020 12:43:03
	System	26 Oct 2020 12:43:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-10-26T07:42:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1bea1e61-ca98-4e46-bd28-69b2aa34628f' User entered '26 Oct 2020 07:42:58'	System	26 Oct 2020 12:43:03
	System	26 Oct 2020 12:43:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 92'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-09T21:18:12', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ef7cac33-9bbb-4702-abb3-db0328470ffb'	System	10 Nov 2020 03:18:28
User entered 'No (N)'	System	10 Nov 2020 03:18:28

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-09T21:18:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ef7cac33-9bbb-4702-abb3-db0328470ffb'	System	10 Nov 2020 03:18:28
User entered 'No (N)'	System	10 Nov 2020 03:18:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-09T21:18:23', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'ef7cac33-9bbb-4702-abb3-db0328470ffb' User entered '09 Nov 2020 21:18:23'	System	10 Nov 2020 03:18:28
	System	10 Nov 2020 03:18:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered 'Day 99'	System	12 Aug 2020 16:50:46

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-16T05:57:14', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1f7a4f2e-1545-4837-b346-566790c4dbf1' User entered 'No (N)'	System	16 Nov 2020 11:57:28
	System	16 Nov 2020 11:57:28

US3552010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-16T05:57:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1f7a4f2e-1545-4837-b346-566790c4dbf1' User entered 'No (N)'	System	16 Nov 2020 11:57:28
	System	16 Nov 2020 11:57:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-16T05:57:25', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1f7a4f2e-1545-4837-b346-566790c4dbf1' User entered '16 Nov 2020 05:57:25'	System	16 Nov 2020 11:57:28
	System	16 Nov 2020 11:57:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:48:35
Data entry locked.	System	12 Aug 2020 16:50:46
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 16:50:46

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-23T22:27:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b05be64c-850c-4a9f-910a-4f1becc44701'	System	24 Nov 2020 04:27:24
User entered 'No (N)'	System	24 Nov 2020 04:27:24

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-23T22:27:12', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b05be64c-850c-4a9f-910a-4f1becc44701' User entered 'No (N)'	System	24 Nov 2020 04:27:24

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-23T22:27:22', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'b05be64c-850c-4a9f-910a-4f1becc44701' User entered '23 Nov 2020 22:27:22'	System	24 Nov 2020 04:27:24
	System	24 Nov 2020 04:27:24

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:19', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973' User entered 'Yes (Y)'	System	27 Nov 2020 14:06:03
	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:32', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973'	System	27 Nov 2020 14:06:03
User entered 'Yes (Y)'	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973'	System	27 Nov 2020 14:06:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973' User entered 'No (N)'	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973' User entered 'No (N)'	System	27 Nov 2020 14:06:03
	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-11-27T08:05:53', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a0b6c7b4-6351-465d-beac-26c614ac8973' User entered '27 Nov 2020 08:05:53'	System	27 Nov 2020 14:06:03
	System	27 Nov 2020 14:06:03

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-05T10:37:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21307fed-cc86-4cd2-9fff-c2b01be43483' User entered 'No (N)'	System	05 Dec 2020 16:37:34
	System	05 Dec 2020 16:37:34

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-05T10:37:25', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21307fed-cc86-4cd2-9fff-c2b01be43483' User entered 'No (N)'	System	05 Dec 2020 16:37:34

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-05T10:37:32', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '21307fed-cc86-4cd2-9fff-c2b01be43483' User entered '05 Dec 2020 10:37:32'	System	05 Dec 2020 16:37:34
	System	05 Dec 2020 16:37:34

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-11T00:08:29', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '375aedic0-a869-438d-adb3-27b326149143' User entered 'No (N)'	System	11 Dec 2020 06:08:47
	System	11 Dec 2020 06:08:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-11T00:08:38', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '375aedc0-a869-438d-adb3-27b326149143' User entered 'No (N)'	System	11 Dec 2020 06:08:47
	System	11 Dec 2020 06:08:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-11T00:08:44', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '375aedc0-a869-438d-adb3-27b326149143' User entered '11 Dec 2020 00:08:44'	System	11 Dec 2020 06:08:47
	System	11 Dec 2020 06:08:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-18T06:03:25', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f0bcc191-ff29-42cf-a60b-9fa6373ecc67'	System	18 Dec 2020 12:03:45
User entered 'No (N)'	System	18 Dec 2020 12:03:45

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-18T06:03:31', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f0bcc191-ff29-42cf-a60b-9fa6373ecc67'	System	18 Dec 2020 12:03:45
User entered 'No (N)'	System	18 Dec 2020 12:03:45

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-18T06:03:41', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f0bcc191-ff29-42cf-a60b-9fa6373ecc67' User entered '18 Dec 2020 06:03:41'	System	18 Dec 2020 12:03:45
	System	18 Dec 2020 12:03:45

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-27T12:06:52', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a7779310-7880-48cd-84bc-11844f53b48f' User entered 'No (N)'	System	27 Dec 2020 18:07:07
	System	27 Dec 2020 18:07:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-27T12:06:58', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a7779310-7880-48cd-84bc-11844f53b48f' User entered 'No (N)'	System	27 Dec 2020 18:07:07
	System	27 Dec 2020 18:07:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2020-12-27T12:07:05', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'a7779310-7880-48cd-84bc-11844f53b48f' User entered '27 Dec 2020 12:07:05'	System	27 Dec 2020 18:07:07
	System	27 Dec 2020 18:07:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-02T09:48:56', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'aeafc2f6-ee02-4287-9aa8-34577f7e4b01' User entered 'No (N)'	System	02 Jan 2021 15:49:12

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-02T09:49:03', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'aeafc2f6-ee02-4287-9aa8-34577f7e4b01'	System	02 Jan 2021 15:49:12
User entered 'No (N)'	System	02 Jan 2021 15:49:12

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-02T09:49:08', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'aeafc2f6-ee02-4287-9aa8-34577f7e4b01' User entered '02 Jan 2021 09:49:08'	System	02 Jan 2021 15:49:12

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-08T13:00:46', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5a31ffca-e7f3-4af3-bbb0-82de626dcb6e' User entered 'No (N)'	System	08 Jan 2021 19:01:05

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-08T13:00:52', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5a31ffca-e7f3-4af3-bbb0-82de626dcb6e' User entered 'No (N)'	System	08 Jan 2021 19:01:05

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-08T13:00:59', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '5a31ffca-e7f3-4af3-bbb0-82de626dcb6e' User entered '08 Jan 2021 13:00:59'	System	08 Jan 2021 19:01:05

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-15T13:01:04', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '85f0f937-a23b-4586-9c58-a90a90ad48f4' User entered 'No (N)'	System	19 Jan 2021 19:25:23
	System	19 Jan 2021 19:25:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-15T13:01:15', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '85f0f937-a23b-4586-9c58-a90a90ad48f4'	System	19 Jan 2021 19:25:23
User entered 'No (N)'	System	19 Jan 2021 19:25:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-15T13:01:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '85f0f937-a23b-4586-9c58-a90a90ad48f4' User entered '15 Jan 2021 13:01:20'	System	19 Jan 2021 19:25:23
	System	19 Jan 2021 19:25:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-22T05:49:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2898f8fc-766f-4e10-9c79-c146b148efae' User entered 'No (N)'	System	22 Jan 2021 11:49:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-22T05:49:20', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2898f8fc-766f-4e10-9c79-c146b148efae' User entered 'No (N)'	System	22 Jan 2021 11:49:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-22T05:49:27', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2898f8fc-766f-4e10-9c79-c146b148efae' User entered '22 Jan 2021 05:49:27'	System	22 Jan 2021 11:49:28
	System	22 Jan 2021 11:49:28

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-29T14:11:32', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1de4631a-1f26-4f81-ba6d-461f2b6298c8' User entered 'No (N)'	System	29 Jan 2021 20:11:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-29T14:11:35', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1de4631a-1f26-4f81-ba6d-461f2b6298c8' User entered 'No (N)'	System	29 Jan 2021 20:11:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-01-29T14:11:42', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '1de4631a-1f26-4f81-ba6d-461f2b6298c8' User entered '29 Jan 2021 14:11:42'	System	29 Jan 2021 20:11:47
	System	29 Jan 2021 20:11:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-06T07:36:02', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '15e9b731-1cff-41c1-a4f3-367ae08e7d8a' User entered 'No (N)'	System	06 Feb 2021 13:36:16
	System	06 Feb 2021 13:36:16

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-06T07:36:06', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '15e9b731-1cff-41c1-a4f3-367ae08e7d8a' User entered 'No (N)'	System	06 Feb 2021 13:36:16

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-06T07:36:11', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '15e9b731-1cff-41c1-a4f3-367ae08e7d8a' User entered '06 Feb 2021 07:36:11'	System	06 Feb 2021 13:36:16
	System	06 Feb 2021 13:36:16

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-12T00:30:27', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '44386821-65f9-4d6d-bc98-e4d5b03bcc2e' User entered 'No (N)'	System	12 Feb 2021 06:30:44
	System	12 Feb 2021 06:30:44

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-12T00:30:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '44386821-65f9-4d6d-bc98-e4d5b03bcc2e' User entered 'No (N)'	System	12 Feb 2021 06:30:44

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-12T00:30:39', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '44386821-65f9-4d6d-bc98-e4d5b03bcc2e' User entered '12 Feb 2021 00:30:39'	System	12 Feb 2021 06:30:44
	System	12 Feb 2021 06:30:44

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-19T11:35:34', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '783bd0aa-e1a3-4867-8d39-2fd74f595907' User entered 'No (N)'	System	19 Feb 2021 17:35:49

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-19T11:35:39', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '783bd0aa-e1a3-4867-8d39-2fd74f595907' User entered 'No (N)'	System	19 Feb 2021 17:35:49

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-19T11:35:47', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '783bd0aa-e1a3-4867-8d39-2fd74f595907' User entered '19 Feb 2021 11:35:47'	System	19 Feb 2021 17:35:49
	System	19 Feb 2021 17:35:49

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-26T05:53:06-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e2df715-f1ef-4fea-a79d-274528ff388a'	System	26 Feb 2021 11:53:23
User entered 'No (N)'	System	26 Feb 2021 11:53:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-26T05:53:11-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e2df715-f1ef-4fea-a79d-274528ff388a'	System	26 Feb 2021 11:53:23
User entered 'No (N)'	System	26 Feb 2021 11:53:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-02-26T05:53:18-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7e2df715-f1ef-4fea-a79d-274528ff388a' User entered '26 Feb 2021 11:53:18'	System	26 Feb 2021 11:53:23
	System	26 Feb 2021 11:53:23

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-05T13:02:33-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3fe8b54f-f51d-4105-9c64-e65771eae55b'	System	05 Mar 2021 19:02:55
User entered 'No (N)'	System	05 Mar 2021 19:02:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-05T13:02:44-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3fe8b54f-f51d-4105-9c64-e65771eae55b'	System	05 Mar 2021 19:02:55
User entered 'No (N)'	System	05 Mar 2021 19:02:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-05T13:02:51-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '3fe8b54f-f51d-4105-9c64-e65771eae55b' User entered '05 Mar 2021 13:02:51'	System	05 Mar 2021 19:02:55
	System	05 Mar 2021 19:02:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-14T08:22:47-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f3df54cc-049d-4a55-a186-d24cc547d7a2'	System	14 Mar 2021 13:23:02
User entered 'No (N)'	System	14 Mar 2021 13:23:02

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-14T08:22:51-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f3df54cc-049d-4a55-a186-d24cc547d7a2'	System	14 Mar 2021 13:23:02
User entered 'No (N)'	System	14 Mar 2021 13:23:02

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-14T08:22:59-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'f3df54cc-049d-4a55-a186-d24cc547d7a2'	System	14 Mar 2021 13:23:02
User entered '14 Mar 2021 08:22:59'	System	14 Mar 2021 13:23:02

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:44:24-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered 'Yes (Y)'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:44:30-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered 'No (N)'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:44:39-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered 'No (N)'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:44:48-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered 'Yes (Y)'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:44:59-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-19T22:45:07-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '4b4a479c-c555-4eb5-b018-6a30ee1cf232'	System	20 Mar 2021 03:45:20
User entered '19 Mar 2021 22:45:07'	System	20 Mar 2021 03:45:20

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-27T09:35:38-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c81f00c1-248a-4d14-9487-4f7658ac24e7'	System	27 Mar 2021 14:35:57
User entered 'No (N)'	System	27 Mar 2021 14:35:57

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-27T09:35:32-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c81f00c1-248a-4d14-9487-4f7658ac24e7'	System	27 Mar 2021 14:35:57
User entered 'No (N)'	System	27 Mar 2021 14:35:57

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-27T09:35:52-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'c81f00c1-248a-4d14-9487-4f7658ac24e7' User entered '27 Mar 2021 09:35:52'	System	27 Mar 2021 14:35:57
	System	27 Mar 2021 14:35:57

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:07-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-ecd7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered 'Yes (Y)'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:13-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-ecd7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered 'No (N)'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:17-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-ecd7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered 'No (N)'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:22-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-ecd7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered 'Yes (Y)'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:26-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-eed7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-02T14:28:31-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e64dc40e-ecd7-4de8-9ddb-47178cefb3c'	System	02 Apr 2021 19:28:42
User entered '02 Apr 2021 14:28:31'	System	02 Apr 2021 19:28:42

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-09T17:08:34-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7618c9a3-c172-4a6b-83f9-82725ea408b3' User entered 'No (N)'	System	09 Apr 2021 22:10:55
	System	09 Apr 2021 22:10:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-09T17:08:38-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7618c9a3-c172-4a6b-83f9-82725ea408b3'	System	09 Apr 2021 22:10:55
User entered 'No (N)'	System	09 Apr 2021 22:10:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-09T17:08:42-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '7618c9a3-c172-4a6b-83f9-82725ea408b3' User entered '09 Apr 2021 17:08:42'	System	09 Apr 2021 22:10:55
	System	09 Apr 2021 22:10:55

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-16T10:10:28-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e2984d39-c74a-4d55-ab3d-9ac86cbbd6a0' User entered 'No (N)'	System	16 Apr 2021 15:10:47
	System	16 Apr 2021 15:10:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-16T10:10:31-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e2984d39-c74a-4d55-ab3d-9ac86cbbd6a0' User entered 'No (N)'	System	16 Apr 2021 15:10:47
	System	16 Apr 2021 15:10:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-16T10:10:38-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: 'e2984d39-c74a-4d55-ab3d-9ac86cbbd6a0' User entered '16 Apr 2021 10:10:38'	System	16 Apr 2021 15:10:47
	System	16 Apr 2021 15:10:47

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-23T13:00:44-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2973e380-64df-42a2-8d90-d6985b430c62'	System	23 Apr 2021 18:00:59
User entered 'No (N)'	System	23 Apr 2021 18:00:59

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-23T13:00:48-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2973e380-64df-42a2-8d90-d6985b430c62'	System	23 Apr 2021 18:00:59
User entered 'No (N)'	System	23 Apr 2021 18:00:59

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-23T13:00:57-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '2973e380-64df-42a2-8d90-d6985b430c62'	System	23 Apr 2021 18:00:59
User entered '23 Apr 2021 13:00:57'	System	23 Apr 2021 18:00:59

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-30T13:03:24-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '05ef619e-be06-4559-acb2-1c2dcd64d3a3'	System	30 Apr 2021 18:04:07
User entered 'No (N)'	System	30 Apr 2021 18:04:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

Have you been exposed to someone with 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 (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-30T13:03:32-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '05ef619e-be06-4559-acb2-1c2dcd64d3a3'	System	30 Apr 2021 18:04:07
User entered 'Yes (Y)'	System	30 Apr 2021 18:04:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-30T13:03:37-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '05ef619e-be06-4559-acb2-1c2dcd64d3a3'	System	30 Apr 2021 18:04:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Apr 2021 18:04:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-04-30T13:03:44-05:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '05ef619e-be06-4559-acb2-1c2dcd64d3a3' User entered '30 Apr 2021 13:03:44'	System	30 Apr 2021 18:04:07
	System	30 Apr 2021 18:04:07

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 04:57:13

**US3552010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:57:13
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 04:57:13

US3552010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:18

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 10:56:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-05T13:02:59-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '635f9f6a-0697-4bd7-9369-e3493c1c0c19'	System	05 Mar 2021 19:03:17
User entered 'No (N)'	System	05 Mar 2021 19:03:17

**US3552010**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:56:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A8A2E9D-FFB6-46C7-8A27-3D015FCF21EF)', Time: '2021-03-05T13:03:04-06:00', User OID: 'PatientReportedOutcome (US3552010)', ODM File OID: '635f9f6a-0697-4bd7-9369-e3493c1c0c19' User entered '05 Mar 2021 13:03:04'	System	05 Mar 2021 19:03:17
	System	05 Mar 2021 19:03:17

US3552010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:21:29

US3552010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered '04 Nov 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	09 Nov 2020 14:11:24
User entered '4 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:21:29

US3552010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:21:29

US3552010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:21:29

US3552010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Dec 2020 16:33:49

**US3552010**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:26:17
User entered 'l'	System	03 Dec 2020 16:33:49

**US3552010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Dec 2020 16:34:01

**US3552010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '03 Dec 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Dec 2020 16:34:01

US3552010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Dec 2020 16:34:01

US3552010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Dec 2020 16:34:01

US3552010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Jan 2021 18:54:26

**US3552010**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered 'I'	System	05 Jan 2021 18:54:26

**US3552010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Jan 2021 18:54:37

US3552010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '05 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Jan 2021 18:54:37

**US3552010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Jan 2021 18:54:37

US3552010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Jan 2021 18:54:37

US3552010

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:12:22

**US3552010**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered 'l'	System	03 Feb 2021 19:12:22

**US3552010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:12:33

**US3552010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '03 Feb 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:12:33

**US3552010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:12:33

US3552010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:12:33

US3552010

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 20:52:24

**US3552010**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered 'I'	System	11 Feb 2021 20:52:24

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:07:05
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:13

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:07:05
User entered '24 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:13

US3552010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:07:05
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:13

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered 'VISIT4'	System	24 Feb 2021 15:40:13

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered empty.	System	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered empty.	System	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered empty.	System	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered empty.	System	29 Mar 2021 19:45:43

US3552010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:17:11
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered empty.	System	29 Mar 2021 19:45:43

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:18**

**Weight (derived)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56

US3552010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:07:05
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	24 Feb 2021 15:55:10
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:18

US3552010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:07:05
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	24 Feb 2021 15:55:10
User entered '24 Feb 2021'	Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:18

US3552010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:42:56

US3552010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:12
User entered '24 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:42:56

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:12
User entered '08:40'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 17:42:56

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered '24 Feb 2021 08:40'	System	01 Mar 2021 17:42:56

US3552010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:07:05
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Feb 2021 15:40:22

**US3552010**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:19:56
User entered 'I'	System	24 Feb 2021 15:40:22

**US3552010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 15:56:37

**US3552010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered '6 Apr 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 15:56:37

**US3552010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 15:56:37

US3552010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 15:56:37

US3552010

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	06 Apr 2021 15:56:40

**US3552010**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:17
User entered 'l'	System	06 Apr 2021 15:56:40

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:15

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:15

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:15

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 19:36:15

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:29

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:18**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:38:43

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:29

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:18**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
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 16:38:43

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:29

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	12 Jan 2021 19:36:29

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:44:56
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	12 Jan 2021 19:36:29
	(b) (4)	

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:44:56
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	12 Jan 2021 19:36:29
	(b) (4)	

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:06:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:29

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:18**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User entered empty.	System	12 Jan 2021 19:36:29

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:18**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User entered empty.	System	12 Jan 2021 19:36:29

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:44

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:44

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '10:49'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:44

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User entered '12 Jan 2021 10:49'	System	12 Jan 2021 19:36:44

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:55

US3552010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:55

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered '10:52'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 19:36:55

**US3552010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:18**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:15
User entered '12 Jan 2021 10:52'	System	12 Jan 2021 19:36:55

US3552010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:06:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:15
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:33:49

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Surveillance diary day 110 subject reported change in health,. Please confirm if subject was contacted and if there is associated adverse event reported. Thank you! ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:56:31
Query 'Surveillance diary day 110 subject reported change in health,. Please confirm if subject was contacted and if there is associated adverse event reported. Thank you! ' answered with 'subject contacted, no adverse event associated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	17 Feb 2021 22:31:29
User opened query 'Surveillance diary day 110 subject reported change in health,. Please confirm if subject was contacted and if there is associated adverse event reported. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	14 Feb 2021 21:23:43
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Nerve compression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 16:53:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 16:53:42
Data point term sent to Coder	System	03 Feb 2021 21:35:02
User entered 'L4 and L5 nerve compression'	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '25 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 21:34:53

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 21:34:53

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	03 Feb 2021 21:37:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 21:37:30
Data point term sent to Coder	System	03 Feb 2021 21:37:03
User entered 'worsening hypertension'	Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '25 Jan 2021'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 21:36:51

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 21:36:51

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
Reviewed for Safety.		25 Mar 2021 12:16:15
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-mRNA-1273-P301000005'	System	23 Mar 2021 15:19:38
User entered 'New'	(b) (4), (b) (6)	23 Mar 2021 15:19:38

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Goiter - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 15:28:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 15:28:44
Data point term sent to Coder	System	07 Apr 2021 15:27:43
User closed query 'CDM Coding, please split the term (EXERTIONAL DYSPNEA R/T THYROID GOITER) into separate records, as 'EXERTIONAL DYSPNEA' and 'THYROID GOITER' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	07 Apr 2021 15:27:09
Query 'CDM Coding, please split the term (EXERTIONAL DYSPNEA R/T THYROID GOITER) into separate records, as 'EXERTIONAL DYSPNEA' and 'THYROID GOITER' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'updated' (Site from System).	Cassandra Zehenny (b) (4)	07 Apr 2021 15:27:09
Signature has been broken.	Cassandra Zehenny (b) (4)	07 Apr 2021 15:26:56
User entered 'THYROID GOITER' reason for change: New Information	Cassandra Zehenny (b) (4)	07 Apr 2021 15:26:56
User opened query 'CDM Coding, please split the term (EXERTIONAL DYSPNEA R/T THYROID GOITER) into separate records, as 'EXERTIONAL DYSPNEA' and 'THYROID GOITER' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4)	07 Apr 2021 07:30:27
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Data point term sent to Coder	System	05 Apr 2021 15:19:58
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:19:52
Coding entries removed.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:19:52
Signature has been broken.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:19:52

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1868 of 2602

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'EXERTIONAL DYSPNEA r/t thyroid goiter' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:19:52
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea exertional, LLT: Exertional dyspnea - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 21:14:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 21:14:41
Data point term sent to Coder	System	24 Mar 2021 21:14:02
Coding entries removed.	Cassandra Zehenny (b) (4)	24 Mar 2021 21:13:18
Signature has been broken.	(b) (4)	
User entered 'exertional dyspnea' reason for change: New Information	Cassandra Zehenny (b) (4)	24 Mar 2021 21:13:18
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 15:20:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 15:20:49
Data point term sent to Coder	System	22 Mar 2021 15:05:10
User entered 'Shortness of breath'	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '16 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date when available.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:38:48
Query 'PV Query: Please provide the event end date when available.' answered with 'please reference the entered end date.' (Site from DM).	Cassandra Zehenny (b) (4)	23 Apr 2021 19:08:44
User opened query 'PV Query: Please provide the event end date when available.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:01:05
User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
DataPoint Un-verified.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Signature has been broken.	(b) (4)	
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
DataPoint Verified.	(b) (4)	
User signature succeeded.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
User entered 'Yes (Y)'	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
	(b) (4), (b) (6)	01 Apr 2021 15:24:11
	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 15:15:57
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Apr 2021 15:15:57
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
Signature has been broken.	(b) (4)	05 Apr 2021 15:15:57
User entered '01 Apr 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Apr 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered empty.	(b) (4)	22 Mar 2021 15:04:46
	Heather Douds (b) (4)	
	(b) (4)	

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 21:59:47
User opened query 'PV Query: Please provide the event end date when available. ' (Site from Safety).		01 Apr 2021 17:11:06
User entered empty.	System	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'Grade 4 (Grade 4)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
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).	(b) (4) System	22 Mar 2021 15:05:12
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	22 Mar 2021 15:04:46
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Mar 2021 15:05:12
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Mar 2021 15:05:12
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:05:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Mar 2021 15:04:46
User entered '0'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	
User entered '20 Mar 2021'	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
User entered '17 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:31:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	
User entered '21 Mar 2021'	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 18:22:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 18:22:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4)	22 Mar 2021 18:22:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 15:04:46
User entered empty.	System	22 Mar 2021 15:04:46
	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 18:22:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 18:22:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4)	22 Mar 2021 18:22:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 15:04:46
User entered empty.	System	22 Mar 2021 15:04:46
	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 15:15:57
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
Signature has been broken.	(b) (4)	05 Apr 2021 15:15:57
User entered '0' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:57
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
Signature has been broken.	(b) (4)	24 Mar 2021 16:20:03
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	24 Mar 2021 16:20:03
User signature succeeded.	(b) (4)	23 Mar 2021 15:18:57
User entered '0'	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	22 Mar 2021 15:04:46
	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:29
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:29
User entered '1' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 16:20:03
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 16:20:03
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered '1'	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 15:04:46
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:10:39
User closed 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)	06 Apr 2021 13:00:45
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated ' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	05 Apr 2021 15:16:02
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	05 Apr 2021 15:15:29
Signature has been broken.	Cassandra Zehenny (b) (4) (b) (4)	05 Apr 2021 15:15:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	05 Apr 2021 15:15:29
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)	01 Apr 2021 17:10:19
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:18:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Did the subject have a medical history of Thyroid goiter ? Was the SAE considered a worsening of the subject's medical history of Thyroid goiter ?' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 01:49:03
User closed query 'PV Query: Thyroid goiter was reported as medical history with out a start date. Please provide a start date if available.' (Site from Safety).		13 Apr 2021 01:49:00
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:35:38
Query 'PV Query: Did the subject have a medical history of Thyroid goiter ? Was the SAE considered a worsening of the subject's medical history of Thyroid goiter ?' answered with 'Inaccurate to enter as "worsening of" as subject was unsure of when the goiter was first diagnosed and had not had follow up. Unsure if goiter had changed since initial diagnosis. Data correct as entered.' (Site from Safety).	Heather Douds (b) (4)	09 Apr 2021 19:28:56
Query 'PV Query: Thyroid goiter was reported as medical history with out a start date. Please provide a start date if available.' answered with 'start date is not available' (Site from Safety).	Heather Douds (b) (4)	09 Apr 2021 19:27:37
User opened query 'PV Query: Did the subject have a medical history of Thyroid goiter ? Was the SAE considered a worsening of the subject's medical history of Thyroid goiter ?' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:44:42
User opened query 'PV Query: Thyroid goiter was reported as medical history with out a start date. Please provide a start date if available.' (Site from Safety).		09 Apr 2021 17:44:14
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User closed query ' PV Query: Please confirm the start date of the Coreg.	(b) (4), (b) (6)	06 Apr 2021 13:01:06
' (Site from Safety).		
User closed query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:00:57

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:00:51
Query ' PV Query: Please confirm the start date of the Coreg.	Cassandra Zehenny (b) (4)	05 Apr 2021 15:17:36
' answered with 'entered correctly' (Site from Safety).		
Query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' answered with 'eCRF reflects these dates' (Site from Safety).	Cassandra Zehenny (b) (4)	05 Apr 2021 15:16:38
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	05 Apr 2021 15:16:08
User entered 'SUBJECT CONTACTED DUE TO EDIARY ENTRY FOR HEALTHCARE PROVIDER CONTACT; REPORTS THIS MORNING THAT SHE HAD SHORTNESS OF BREATH STARTING 3/16 WITH DESATURATIONS INTO THE 80S; CONTACTED PCP WHO BELIEVED THIS TO BE A SIDE EFFECT OF MEDICATION (COREG). MEDICATION STOPPED ON 3/16, AND SUBJECT HAD EKG PERFORMED BY PCP THAT WAS ABNORMAL; PCP SENT SUBJECT TO ED. SUBJECT WAS ADMITTED OVERNIGHT FOR CT AND STRESS TEST; PER SUBJECT, WAS NOTED TO HAVE ENLARGED GOITER IN NECK THAT WAS COMPRESSING TRACHEA AND LUNG NODULES ON CT. SUBJECT SCHEDULED TO FOLLOW UP WITH PULMONOLOGY TOMORROW. COVID TEST IN ED WAS NEGATIVE. MEDICAL RECORDS SENT TO SPONSOR ON 3/24. Update as of 05APR- subject had thyroid goiter removed on 31MAR and states that all symptoms have resolved. Placed on 50mcg PO Synthroid daily.' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:15:29

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the start date of the Coreg.    ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:13:15
User opened query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' (Site from Safety).		05 Apr 2021 13:13:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' (Site from Safety).		05 Apr 2021 13:12:40
User closed query 'PV Query: Please confirm the start date of the Coreg.		02 Apr 2021 17:01:23
' (Site from Safety).		
User closed query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' (Site from Safety).		02 Apr 2021 17:01:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' (Site from Safety).		02 Apr 2021 17:01:20
DataPoint Un-verified.	Heather Douds (b) (4)	01 Apr 2021 19:34:24
Signature has been broken.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:34:24

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED DUE TO EDIARY ENTRY FOR HEALTHCARE PROVIDER CONTACT; REPORTS THIS MORNING THAT SHE HAD SHORTNESS OF BREATH STARTING 3/16 WITH DESATURATIONS INTO THE 80S; CONTACTED PCP WHO BELIEVED THIS TO BE A SIDE EFFECT OF MEDICATION (COREG). MEDICATION STOPPED ON 3/16, AND SUBJECT HAD EKG PERFORMED BY PCP THAT WAS ABNORMAL; PCP SENT SUBJECT TO ED. SUBJECT WAS ADMITTED OVERNIGHT FOR CT AND STRESS TEST; PER SUBJECT, WAS NOTED TO HAVE ENLARGED GOITER IN NECK THAT WAS COMPRESSING TRACHEA AND LUNG NODULES ON CT. SUBJECT SCHEDULED TO FOLLOW UP WITH PULMONOLOGY TOMORROW. COVID TEST IN ED WAS NEGATIVE. MEDICAL RECORDS SENT TO SPONSOR ON 3/24' reason for change: New Information	Heather Douds (b) (4)	01 Apr 2021 19:34:24
Query 'PV Query: Please confirm the start date of the Coreg.	Heather Douds (b) (4)	01 Apr 2021 19:33:24
' answered with 'updated' (Site from Safety). Query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' answered with 'updated' (Site from Safety).	Heather Douds (b) (4)	01 Apr 2021 19:31:44
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' answered with 'subject did not receive any interventions at this time' (Site from Safety).	Heather Douds (b) (4)	01 Apr 2021 19:31:18
User opened query 'PV Query: Please confirm the start date of the Coreg.	(b) (4), (b) (6)	01 Apr 2021 17:12:33

' (Site from Safety).

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per medical records, the subject was admitted to the hospital on 16 Mar 2021 and discharged on 17 Mar 2021. Please update the eCRF to reflect these dates. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 17:12:17
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. ' (Site from Safety).		01 Apr 2021 17:11:29
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 21:14:14
	(b) (4)	
User entered 'SUBJECT CONTACTED DUE TO EDIARY ENTRY FOR HEALTHCARE PROVIDER CONTACT; REPORTS THIS MORNING THAT SHE HAD SHORTNESS OF BREATH STARTING 3/16 WITH DESATURATIONS INTO THE 80S; CONTACTED PCP WHO BELIEVED THIS TO BE A SIDE EFFECT OF MEDICATION (COREG). MEDICATION STOPPED ON 3/20, AND SUBJECT HAD EKG PERFORMED BY PCP THAT WAS ABNORMAL; PCP SENT SUBJECT TO ED. SUBJECT WAS ADMITTED OVERNIGHT FOR CT AND STRESS TEST; PER SUBJECT, WAS NOTED TO HAVE ENLARGED GOITER IN NECK THAT WAS COMPRESSING TRACHEA AND LUNG NODULES ON CT. SUBJECT SCHEDULED TO FOLLOW UP WITH PULMONOLOGY TOMORROW. COVID TEST IN ED WAS NEGATIVE. medical records sent to sponsor on 3/24' reason for change: New Information	Cassandra Zehenny (b) (4)	24 Mar 2021 21:14:14
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject contacted due to eDiary entry for healthcare provider contact; reports this morning that she had shortness of breath starting 3/16 with desaturations into the 80s; contacted PCP who believed this to be a side effect of medication (Coreg). Medication stopped on 3/20, and subject had EKG performed by PCP that was abnormal; PCP sent subject to ED. Subject was admitted overnight for CT and stress test; per subject, was noted to have enlarged goiter in neck that was compressing trachea and lung nodules on CT. Subject scheduled to follow up with pulmonology tomorrow. COVID test in ED was negative.'	Heather Douds (b) (4) (b) (4)	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 15:04:46

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 15:22:38

Adverse event

PRODUCTION RELEASE (v12.003  
EAB) (1725)

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:24:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:24:05
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
Data point term sent to Coder System	(b) (4)	24 Mar 2021 21:13:01
User entered 'Right pulmonary nodule'	Cassandra Zehenny (b) (4)	24 Mar 2021 21:12:54
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '16 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
User entered empty.	System	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.	(b) (4)	12 Apr 2021 16:36:24
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Yes (Y)'	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 21:12:54
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.	(b) (4)	12 Apr 2021 16:36:26
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
User entered '24 Mar 2021' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 21:12:54
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
User entered empty.	System	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.	(b) (4)	12 Apr 2021 16:36:30
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 16:38:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	06 Apr 2021 16:38:36
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Cassandra Zehenny (b) (4)	24 Mar 2021 21:12:54
	(b) (4)	

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

US3552010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
DataPoint Verified.		01 Apr 2021 15:24:11
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 21:12:54

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
User entered '0'	System	24 Mar 2021 21:12:54

**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:38
User entered 'I'	System	24 Mar 2021 21:12:54

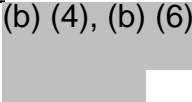
**US3552010**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 15:22:38

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:06:18

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:37:10
Query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'ConMeds #2 and #3' (Site from DM).	Cassandra Zehenny (b) (4)	08 Feb 2021 22:01:21
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:18:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	12 Aug 2020 19:12:17

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:31:11
Data point term sent to Coder	System	12 Aug 2020 19:30:08
User entered 'atorvastatin'	Stanley Doublin (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'high cholesterol'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '20'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:39:16
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:34:35
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:29:32
User entered 'un UNK 2013'	Stanley Doublin (b) (4)	12 Aug 2020 19:29:32
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:29:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:29:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:29:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:29:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:33:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:33:13
Data point term sent to Coder	System	12 Aug 2020 19:32:13
User entered 'losartan'	Stanley Doublin (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'hypertension'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '100'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:39:46
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:34:27
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:32:12
User entered 'un UNK 2005'	Stanley Doublin (b) (4)	12 Aug 2020 19:32:12
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:32:12

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:32:12

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:32:12

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:32:12

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:40:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:40:11
Data point term sent to Coder	System	12 Aug 2020 19:39:25
User entered 'Diltiazem er'	Stanley Doublin (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'hypertension'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '240'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:06:18**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:40:07
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:38:44
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:38:32
User entered 'un UNK 2000'	Stanley Doublin (b) (4)	12 Aug 2020 19:38:32
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:38:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:38:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:38:32

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:38:32

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:43:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:43:08
Data point term sent to Coder	System	12 Aug 2020 19:42:36
User entered 'symbicort'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'asthma'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:07:12
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' answered with 'exact dose unknown, self reported' (Site from DM).	Heather Douds (b) (4) (b) (4)	05 Oct 2020 13:45:52
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:13:53
User entered 'I'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'puff (PUFF)'	(b) (4) Stanley Dublin (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Dublin (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	13 Aug 2020 05:40:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:41:57
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:41:51
User entered 'un Feb 2020'	Stanley Doublin (b) (4)	12 Aug 2020 19:41:51
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '11 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	12 Aug 2020 19:41:51

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User entered 'I'	System	12 Aug 2020 19:41:51

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User entered 'I'	System	12 Aug 2020 19:41:51

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:01
User entered '804 (804)'	System	12 Aug 2020 19:41:51

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:44:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:44:25
Data point term sent to Coder	System	12 Aug 2020 19:43:37
User entered 'duloxetine'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'anxiety'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '60'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:41:21
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:43:30
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:43:22
User entered 'un Jul 2019'	Stanley Doublin (b) (4)	12 Aug 2020 19:43:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:43:22

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:43:22

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:43:22

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:43:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 07:42:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 07:42:23
Data point term sent to Coder	System	12 Aug 2020 19:47:45
User entered 'bupropion er'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'anxiety'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '150'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:41:41
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:47:04
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:46:57
User entered 'un Sep 2019'	Stanley Doublin (b) (4)	12 Aug 2020 19:46:57
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:46:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:46:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:46:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:46:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:50:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:50:09
Data point term sent to Coder	System	12 Aug 2020 19:48:47
User entered 'spironolactone'	Stanley Doublin (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'hypertension'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '50'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:43:32
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:48:32
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:48:24
User entered 'un UNK 2019'	Stanley Doublin (b) (4)	12 Aug 2020 19:48:24
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:48:24

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:48:24

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:48:24

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:48:24

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:50:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:50:10
Data point term sent to Coder	System	12 Aug 2020 19:49:48
User entered 'hydrochlorothiazide'	Stanley Doublin (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'hypertension'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '25'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:44:04
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:49:52
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:49:45
User entered 'un UNK 2013'	Stanley Doublin (b) (4)	12 Aug 2020 19:49:45
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:49:45

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:49:45

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:49:45

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:49:45

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:56:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:56:07
Data point term sent to Coder	System	12 Aug 2020 19:54:55
User entered 'ropinirole'	Stanley Doublin (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'restless leg syndrome'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. '(Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'exact dose unknown, self reported' (Site from DM). User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. '(Site from DM). User entered 'I'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4), (b) (6) Stanley Doublin (b) (4)	09 Oct 2020 12:07:40 05 Oct 2020 13:49:38 05 Oct 2020 08:40:24 12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User closed query 'Per hospital record, dose unit is 1 mg. Please review if mg can be used instead of tablet. Thank you! ' (Site from CRA).	(b) (4)	
Query 'Per hospital record, dose unit is 1 mg. Please review if mg can be used instead of tablet. Thank you! ' answered with 'updated thank you ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 16:56:28
Signature has been broken.	Cassandra Zehenny (b) (4)	01 Apr 2021 15:59:00
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per hospital record, dose unit is 1 mg. Please review if mg can be used instead of tablet. Thank you! ' (Site from CRA).	Cassandra Zehenny (b) (4)	01 Apr 2021 15:58:39
User signature succeeded.	(b) (4)	
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	01 Apr 2021 15:38:52
	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
	Stanley Doublin (b) (4)	12 Aug 2020 19:54:41
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:44:42
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:54:47
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:54:41
User entered 'un Sep 2017'	Stanley Doublin (b) (4)	12 Aug 2020 19:54:41
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:54:41

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 19:54:41

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 19:54:41

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 19:54:41

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 23:28:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:28:18
Data point term sent to Coder	System	12 Aug 2020 19:55:56
User entered 'calcium carbonate'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	11 Nov 2020 15:49:52
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:16:31
Query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' answered with 'Not prophylaxis, data correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	05 Oct 2020 13:50:54
User opened query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:14:48
User entered 'health'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:07:56
Query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Exact dose unknown, self reported' (Site from DM).	Heather Douds (b) (4)	05 Oct 2020 13:51:11
User opened query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:14:29
User entered 'I'	Stanley Doublin (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:44:58
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:56:01
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:55:55
User entered 'un UNK 2005'	Stanley Doublin (b) (4)	12 Aug 2020 19:55:55
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:55:55

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:55:55

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:55:55

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:55:55

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 19:59:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:59:14
Data point term sent to Coder	System	12 Aug 2020 19:57:59
User entered 'zyrtec'	Stanley Doublin (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'seasonal allergies'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '10'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:45:24
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 19:57:20
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:57:11
User entered 'un UNK 2010'	Stanley Doublin (b) (4)	12 Aug 2020 19:57:11
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:11

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 19:57:11

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 19:57:11

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:57:11

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED PE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 09:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 09:37:47
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Data point term sent to Coder	System	06 Apr 2021 14:55:46
User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	System	06 Apr 2021 14:54:46
' (Site from System).		
Query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:46
' answered with 'updated' (Site from System).		
Data point term sent to Coder	System	06 Apr 2021 14:54:45
Coding entries removed.	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
Signature has been broken.	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
User entered 'SUDAFED [phenylephrine]' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	06 Apr 2021 12:21:01
' (Site from System).		
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:03:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:03:09
Data point term sent to Coder	System	12 Aug 2020 20:02:15
Data point term sent to Coder	System	12 Aug 2020 19:58:00
User entered 'sudafed'	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 20:01:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 19:57:31
User entered empty.	System	12 Aug 2020 19:57:31
	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'seasonal allergies' reason for change: Data Entry Error	System	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
User entered empty.	(b) (4)	
	System	12 Aug 2020 19:57:31
	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
	(b) (4)	
User entered '10' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:01:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered '1' reason for change: Data Entry Error	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:57:31
User entered empty.	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	06 Apr 2021 14:54:40
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:01:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:57:31
User entered empty.	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'once daily (QD)' reason for change: Data Entry Error	System	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
User entered empty.	(b) (4)	
	System	12 Aug 2020 19:57:31
	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'Oral (ORAL)' reason for change: Data Entry Error	System	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
User entered empty.	(b) (4)	
	System	12 Aug 2020 19:57:31
	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:46:01
answered with 'data is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 20:01:27
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:01:23
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 20:01:23
User entered 'un Feb 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 19:57:31
User entered empty.	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	12 Aug 2020 20:01:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:57:31
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:01:23
User entered 'No (N)' reason for change: Data Entry Error	System	12 Aug 2020 20:01:23
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Doublin (b) (4)	12 Aug 2020 20:01:23
User entered empty.	(b) (4)	
	System	12 Aug 2020 19:57:31
	Stanley Doublin (b) (4)	12 Aug 2020 19:57:31
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 20:01:23
User entered empty.	System	12 Aug 2020 19:57:31

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 20:01:23
User entered empty.	System	12 Aug 2020 19:57:31

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:01:23
User entered empty.	System	12 Aug 2020 19:57:31

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 13:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 13:04:27
Data point term sent to Coder	System	12 Aug 2020 20:03:19
User entered 'multivitamin'	Stanley Doublin (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	11 Nov 2020 15:34:49
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'health'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'I'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:46:15
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 20:03:28
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:03:18
User entered 'un UNK 2015'	Stanley Doublin (b) (4)	12 Aug 2020 20:03:18
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:03:18

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 20:03:18

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:03:18

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:03:18

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 20:05:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:05:08
Data point term sent to Coder	System	12 Aug 2020 20:04:23
User entered 'vitamin d3'	Stanley Doublin (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Stanley Doublin (b) (4)	11 Nov 2020 15:34:56
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 09:30:17
Query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' answered with 'Data correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	05 Oct 2020 13:51:41
User opened query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:15:17
User entered 'health'	Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	09 Oct 2020 12:08:06
' (Site from DM). Query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	Heather Douds (b) (4)	05 Oct 2020 13:51:26
' answered with 'Exact dose unknown, self reported' (Site from DM). User opened query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	05 Oct 2020 13:15:10
' (Site from DM). User entered 'I'	Stanley Doublin (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 05:46:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 20:05:01
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:04:55
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 20:04:55
User entered 'un UNK 2013' reason for change: Data Entry Error	Stanley Doublin (b) (4)	12 Aug 2020 20:04:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Aug 2020 20:04:21
User entered empty.	Stanley Doublin (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:04:55
User entered 'Yes (Y)' reason for change: Data Entry Error	System	12 Aug 2020 20:04:55
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Doublin (b) (4)	12 Aug 2020 20:04:55
User entered empty.	(b) (4)	
	System	12 Aug 2020 20:04:21
	Stanley Doublin (b) (4)	12 Aug 2020 20:04:21
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty; reason for change Data Entry Error	(b) (4) Stanley Doublin (b) (4)	12 Aug 2020 20:04:55
User entered 'un UNK 2013'	(b) (4) Stanley Doublin (b) (4)	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:04:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 20:04:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:04:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:04:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 20:07:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:07:24
Data point term sent to Coder	System	12 Aug 2020 20:06:27
User entered 'xanax'	Stanley Doublin (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'anxiety'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '.25'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:46:46
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 20:06:04
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:06:01
User entered 'un UNK 2014'	Stanley Doublin (b) (4)	12 Aug 2020 20:06:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:06:01

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:06:01

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:06:01

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:06:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 20:13:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:13:16
Data point term sent to Coder	System	12 Aug 2020 20:12:43
User entered 'melatonin'	Stanley Doublin (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'insomnia'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. '(Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Exact dose unknown, self reported' (Site from DM). User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. '(Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4) (b) (4), (b) (6) Stanley Doublin (b) (4) (b) (4)	09 Oct 2020 12:08:14 05 Oct 2020 13:51:49 05 Oct 2020 13:15:41 12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'tablet (TABLET)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once daily (QD)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	13 Aug 2020 05:47:22
answered with 'data is correct' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stanley Doublin (b) (4)	12 Aug 2020 20:12:00
answered with 'data is correct' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:11:56
User entered 'un UNK 2017'	Stanley Doublin (b) (4)	12 Aug 2020 20:11:56
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Aug 2020 20:11:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Aug 2020 20:11:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:11:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:11:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:32
Data point term sent to Coder	System	05 Oct 2020 16:04:55
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 16:04:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:16:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:16:09
Data point term sent to Coder	System	13 Aug 2020 19:14:42
User entered 'tylenol'	Stanley Doublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:53:56
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated per query request' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 16:04:33
User entered 'PAIN- injection site' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 16:04:01
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:41:13
User entered 'pain'	Stanley Doublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '500'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	18 Aug 2020 14:32:48
User entered 'once (ONCE)'	Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '12 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered '13 Aug 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	18 Aug 2020 14:32:48
User entered '12 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:06:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' answered with 'within 7 day post injection period, therefore not an AE' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 16:04:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:06:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:40:57
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User entered empty.	System	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User entered empty.	System	13 Aug 2020 19:13:56

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:09
User entered empty.	System	13 Aug 2020 19:13:56

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 17:36:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 17:36:30
Data point term sent to Coder	System	19 Aug 2020 17:35:30
User entered 'Tylenol'	Heather Douds (b) (4)	19 Aug 2020 17:34:40
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 06 Oct 2020 13:20:51
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'osteoarthritis pain prophylaxis, data correct as entered' (Site from DM).	Heather Douds (b) (4)	05 Oct 2020 13:52:54
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 05 Oct 2020 08:41:45
User entered 'Yes (Y)'	Heather Douds (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Osteoarthritis'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '1000'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:06:18**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System (b) (4)	19 Aug 2020 17:34:53
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 17:34:40
User entered empty.	Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '1' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	19 Aug 2020 17:34:53
User entered '0'	(b) (4) Heather Douds (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 17:34:53
User entered 'No (N)' reason for change: Data Entry Error	System	19 Aug 2020 17:34:53
User opened query 'Data is required. Please complete.' (Site from System).	Heather Douds (b) (4)	19 Aug 2020 17:34:53
User entered empty.	(b) (4)	
	System	19 Aug 2020 17:34:40
	Heather Douds (b) (4)	19 Aug 2020 17:34:40
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:34:40

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:34:40

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:34:40

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 17:37:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 17:37:33
Data point term sent to Coder	System	19 Aug 2020 17:36:33
Data point term sent to Coder	System	19 Aug 2020 17:35:30
User entered 'Ibuprofen'	Heather Douds (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:21:20
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'osteoarthritis pain prophylaxis, data correct as entered' (Site from DM).	Heather Douds (b) (4)	05 Oct 2020 13:53:15
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:16:09
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 17:35:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 17:35:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	19 Aug 2020 17:35:32
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 17:35:21
User entered empty.	Heather Douds (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 17:35:32
User entered 'Osteoarthritis' reason for change: Data Entry Error	Heather Douds (b) (4)	19 Aug 2020 17:35:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Aug 2020 17:35:21
	Heather Douds (b) (4)	19 Aug 2020 17:35:21
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '400'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:06:18**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	19 Aug 2020 17:35:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:35:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:35:21

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:35:21

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
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)	08 Sep 2020 18:52:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:52:54
Data point term sent to Coder User entered 'Tylenol'	System Heather Doubs (b) (4)	08 Sep 2020 18:51:51 08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:55:59
Query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptom occurred within 7 day diary period and therefore considered AR, not an AE. Thank you. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 15:57:11
User opened query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:49:20
User entered 'Injection site pain'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered '1000'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	09 Sep 2020 15:18:43
User entered 'as needed (PRN)' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Sep 2020 15:18:43
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
User entered 'once (ONCE)'	System	09 Sep 2020 15:18:37
	Heather Douds (b) (4)	08 Sep 2020 18:51:28
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	09 Nov 2020 14:11:56
User entered '7 Sep 2020'	(b) (4)	
	Heather Douds (b) (4)	08 Sep 2020 18:51:28
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered '0'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	09 Nov 2020 14:11:56
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Sep 2020 15:18:37
	(b) (4)	
User entered '7 Sep 2020'	Heather Douds (b) (4)	08 Sep 2020 18:51:28
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:01:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'AR, not AE per protocol' (Site from DM).	Heather Douds (b) (4)	02 Oct 2020 18:18:18

US3552010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Oct 2020 12:35:36 08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User entered empty.	System	08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User entered empty.	System	08 Sep 2020 18:51:28

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:19
User entered empty.	System	08 Sep 2020 18:51:28

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:53:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:53:59
Data point term sent to Coder	System	08 Sep 2020 18:52:57
User entered 'Ibuprofen'	Heather Douds (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:57:12
Query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptom occurred within 7 day diary period and therefore considered AR, not an AE. Thank you. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 15:57:22
User opened query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:49:38
User entered 'Injection site pain'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered '400'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered empty.	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	09 Sep 2020 15:18:57
User entered 'once (ONCE)'	(b) (4)	
	Heather Douds (b) (4)	08 Sep 2020 18:51:57
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered empty.	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	09 Nov 2020 14:12:29
User entered '7 Sep 2020'	(b) (4)	
	Heather Douds (b) (4)	08 Sep 2020 18:51:57
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Heather Douds (b) (4)	08 Sep 2020 18:51:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	09 Nov 2020 14:12:29
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	09 Sep 2020 15:18:57
	(b) (4)	
User entered '7 Sep 2020'	Heather Douds (b) (4)	08 Sep 2020 18:51:57
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:01:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'AR, not AE per protocol' (Site from DM).	Heather Douds (b) (4) (b) (4)	02 Oct 2020 18:18:53

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:06:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	02 Oct 2020 12:35:46 08 Sep 2020 18:51:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User entered empty.	System	08 Sep 2020 18:51:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User entered empty.	System	08 Sep 2020 18:51:57

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:21
User entered empty.	System	08 Sep 2020 18:51:57

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
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) (b) (4)	04 Feb 2021 17:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:07:46
Data point term sent to Coder	System	04 Feb 2021 17:07:09
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 17:06:47
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) (b) (4)	07 Oct 2020 17:48:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:48:16
Data point term sent to Coder	System	07 Oct 2020 17:47:36
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	07 Oct 2020 17:46:59
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) (b) (4)	28 Sep 2020 23:35:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:35:49
Data point term sent to Coder	System	28 Sep 2020 17:19:11
User entered 'influenza vaccine'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Feb 2021 17:06:47
User entered 'Prophylaxis' reason for change: Data Entry Error	Stanley Doublin (b) (4)	07 Oct 2020 17:46:59
User entered 'prevention of Flu'	Stanley Doublin (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'l'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'shot'	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'once (ONCE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '27 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '27 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 17:18:49

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User entered empty.	System	28 Sep 2020 17:18:49

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User entered empty.	System	28 Sep 2020 17:18:49

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:25
User entered empty.	System	28 Sep 2020 17:18:49

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:42
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4)	04 Mar 2021 16:03:00 04 Mar 2021 16:02:08
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Feb 2021 19:17:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 19:17:27
Data point term sent to Coder User entered 'carvedilol'	System Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:11 03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:49:12
User closed query 'Per DM CLR: Pleas confirm if this Con Med was given for AE #2. If yes, please update Con Med indication to reflect AE condition #2 as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 08 Mar 2021 10:07:41
Query 'Per DM CLR: Pleas confirm if this Con Med was given for AE #2. If yes, please update Con Med indication to reflect AE condition #2 as appropriate.' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	04 Mar 2021 16:02:18
Signature has been broken.	(b) (4)	Heather Douds (b) (4) 04 Mar 2021 16:02:08
User entered 'HYPERTENSION, worsening hypertension' reason for change: Data Entry Error	Heather Douds (b) (4)	04 Mar 2021 16:02:08
User opened query 'Per DM CLR: Pleas confirm if this Con Med was given for AE #2. If yes, please update Con Med indication to reflect AE condition #2 as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 04 Mar 2021 03:12:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'hypertension'	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:49:12
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:07:43
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	04 Mar 2021 16:02:28
Signature has been broken.	Heather Douds (b) (4) (b) (4)	04 Mar 2021 16:02:08
User entered '3.125' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	04 Mar 2021 16:02:08
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 03:10:53
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User entered '3 / 25'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'twice daily (BID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:33:45
	(b) (4)	
User entered '06 Feb 2021' reason for change: Data Entry Error	Heather Douds (b) (4)	01 Apr 2021 19:33:45
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
User entered '02 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:15:54
	(b) (4)	

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	22 Mar 2021 15:49:00
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	22 Mar 2021 15:49:00
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	03 Feb 2021 19:15:54
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	01 Apr 2021 19:33:45
	(b) (4)	
User entered '16 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	01 Apr 2021 19:33:45
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:18:57
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	22 Mar 2021 15:49:00
	(b) (4)	
User entered '20 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	22 Mar 2021 15:49:00
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:15:54
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:15:54

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User entered '2'	System	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User entered 'I'	System	03 Feb 2021 19:15:54

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:38
User entered '804 (804)'	System	03 Feb 2021 19:15:54

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Feb 2021 21:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Feb 2021 21:11:48
Data point term sent to Coder	System	04 Feb 2021 19:33:20
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
Data point term sent to Coder	System	03 Feb 2021 19:19:16
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
Data point term sent to Coder	System	03 Feb 2021 19:17:11
User entered 'Prednisone'	Mikayla Frye (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'nerve compression'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered '40'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered empty.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered empty.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered empty.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered '02 Feb 2021'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered '0'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
User entered 'No (N)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:16:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:16:42
User entered '04 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:16:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:36
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
User entered 'I'	System	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
User entered 'I'	System	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:42
DataPoint activated with code reason code Data required.	Cassandra Zehenny (b) (4)	04 Feb 2021 19:33:04
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:36
User entered '804 (804)'	System	03 Feb 2021 19:16:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:53
Data point term sent to Coder	System	11 Feb 2021 15:08:43
DataPoint activated with code reason code Data required.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 15:08:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:11:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:11:49
Data point term sent to Coder	System	03 Feb 2021 19:19:16
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:42
Data point term sent to Coder	System	03 Feb 2021 19:18:15
User entered 'prednisone'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'nerve compression'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered '30' reason for change: Data Entry Error	Mikayla Frye (b) (4)	03 Feb 2021 19:18:25
	(b) (4)	
User entered '20'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'mg (mg)'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4) Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User entered empty.	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:17:22
User entered '05 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered '0'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4) Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Feb 2021 15:08:11
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:18:25
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:18:25
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:18:25
User entered '07 Feb 2021' reason for change: Data Entry Error	Mikayla Frye (b) (4)	03 Feb 2021 19:18:25
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:17:22
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:17:22
User entered '08 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
User entered '08 Feb 2021'	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:11
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	03 Feb 2021 19:17:22
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User entered 'l'	(b) (4)	
	System	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User entered 'I'	(b) (4)	
	System	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:52
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:42
User entered '804 (804)'	(b) (4)	
	System	03 Feb 2021 19:17:22

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:54
Data point term sent to Coder	System	11 Feb 2021 15:08:42
DataPoint activated with code reason code Data required.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 15:08:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:11:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:11:49
Data point term sent to Coder	System	03 Feb 2021 19:19:16
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:50
Data point term sent to Coder	System	03 Feb 2021 19:18:14
User entered 'prednisone'	Mikayla Frye (b) (4) (b) (4)	03 Feb 2021 19:18:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'nerve compression'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered '20'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'mg (mg)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered empty.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:18:01
User entered '08 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4) Heather Douds (b) (4)	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
User entered '0'	(b) (4) Mikayla Frye (b) (4)	03 Feb 2021 19:18:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:18:01
User entered '09 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:18
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	03 Feb 2021 19:18:01
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
User entered 'l'	(b) (4)	
	System	03 Feb 2021 19:18:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
User entered 'I'	(b) (4)	
	System	03 Feb 2021 19:18:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:43:56
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:18:50
User entered '804 (804)'	(b) (4)	
	System	03 Feb 2021 19:18:01

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User closed query 'Please add aminophylline 250mg/10ml injection 100mg during hospital stay on 17Mar2021. ' (Site from CRA).	(b) (4)	05 Apr 2021 16:55:38
Query 'Please add aminophylline 250mg/10ml injection 100mg during hospital stay on 17Mar2021. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:26:07
User opened query 'Please add aminophylline 250mg/10ml injection 100mg during hospital stay on 17Mar2021. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:40:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:22:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:52:48
Data point term sent to Coder	System	12 Feb 2021 17:51:53
DataPoint activated with code reason code Data required.	Heather Douds (b) (4) (b) (4)	12 Feb 2021 17:50:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:55
Data point term sent to Coder	System	11 Feb 2021 15:09:44
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	11 Feb 2021 15:08:49
Data point term sent to Coder	System	11 Feb 2021 15:08:43

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2419 of 2602

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
Data point term sent to Coder	(b) (4)	
DataPoint inactivated with code reason code Data not required.	System	03 Feb 2021 19:20:17
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
	(b) (4)	
User entered 'prednisone'	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'No (N)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'nerve compression'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered '10'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'mg (mg)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'once daily (QD)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'Oral (ORAL)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:49
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
	System	11 Feb 2021 15:08:23
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:19:42
User entered '10 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered '0'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	
	(b) (4)	03 Feb 2021 19:19:56
User entered 'No (N)'	Mikayla Frye (b) (4)	
	(b) (4)	03 Feb 2021 19:19:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	System	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '12 Feb 2021'	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
	(b) (4)	
	System	03 Feb 2021 19:19:42
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:26
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'No (N)'	(b) (4)	
	Mikayla Frye (b) (4)	03 Feb 2021 19:19:42
	(b) (4)	

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'I'	System	03 Feb 2021 19:19:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered 'I'	System	03 Feb 2021 19:19:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:06:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:00
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Feb 2021 17:50:58
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	11 Feb 2021 15:08:49
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	11 Feb 2021 15:08:23
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	03 Feb 2021 19:19:56
User entered '804 (804)'	System	03 Feb 2021 19:19:42

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: XANTHINES, PRODUCT: AMINOPHYLLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 08:13:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:13:56
Data point term sent to Coder	System	01 Apr 2021 19:28:17
User entered 'aminophylline 250 mg/10 mL'	Heather Douds (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'pulmonary nodule'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'injection'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '17 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '17 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
DataPoint Verified.		12 Apr 2021 16:39:59
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
User entered empty.	System	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
User entered empty.	System	01 Apr 2021 19:28:07

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:44:08
User entered empty.	System	01 Apr 2021 19:28:07

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 15:19:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 15:19:26
Data point term sent to Coder	System	05 Apr 2021 15:18:57
User entered 'synthroid'	Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'post-thyroid goiter removal'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '50'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'ug (ug)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'once daily (QD)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'Oral (ORAL)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '02 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:06:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:06:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:48

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:06:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Apr 2021 15:18:48

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 15:18:48

**US3552010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:06:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 15:18:48

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:06:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:15
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:37:03
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User closed query 'Per ETRTR: According to SAE page "Shortness of Breath", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA). Signature has been broken.	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4)	07 Apr 2021 18:05:11 05 Apr 2021 15:17:47
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	05 Apr 2021 15:17:47
Query 'Per ETRTR: According to SAE page "Shortness of Breath", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	24 Mar 2021 16:20:14
User opened query 'Per ETRTR: According to SAE page "Shortness of Breath", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:41:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:22:49
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	18 Feb 2021 15:50:34

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:36:48
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '31 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:06

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:36:48
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'thyroid goiter removal'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:06

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:18

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:36:48
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'Adverse Event (AE)'	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:06

US3552010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:18

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:36:48
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	05 Apr 2021 15:18:06

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.		12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.		12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 19:27:20

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered '23/Mar/2021 11:19'	(b) (4) System	23 Mar 2021 15:19:49

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:18

**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)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'l'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:18

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered '25/Mar/2021 08:16'	(b) (4) System	25 Mar 2021 12:16:52

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:18

**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)	02 Apr 2021 17:01:37
DataPoint Verified.		01 Apr 2021 15:24:46
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:55:31
User entered 'l'	(b) (4), (b) (6)	25 Mar 2021 12:16:52

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '02/Apr/2021 12:01'	(b) (4) System	02 Apr 2021 17:01:52

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:06:18

**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)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:10:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:01:22
User entered 'l'		02 Apr 2021 17:01:52

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 19:27:20

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered '06/Apr/2021 09:01'	(b) (4) System	06 Apr 2021 13:01:36

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:06:18

**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)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:10:39
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:01:36

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered '07/Apr/2021 16:20'	(b) (4) System	07 Apr 2021 20:20:36

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:06:18

**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)	12 Apr 2021 16:37:20
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:26:14
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 20:20:36

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:31
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered	(b) (4)	23 Mar 2021 15:19:38
'USA-US089-2021-MRNA-1273-P301000005'	System	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'Yes (Y)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'No (N)'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'sharon'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'frey'	(b) (4) System	23 Mar 2021 15:19:38

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:18

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:11
User entered empty.	System	12 Apr 2021 13:48:18
User entered '1100 S. Grand Blvd'	Heather Douds (b) (4) (b) (4)	09 Apr 2021 19:27:20

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered 'Saint Louis'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'MO'	(b) (4) System	23 Mar 2021 15:19:38

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered empty.	System	12 Apr 2021 13:48:18
User entered '63104'	Heather Douds (b) (4)	09 Apr 2021 19:27:20
	(b) (4)	

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:24:46
Reviewed for Safety.		25 Mar 2021 12:16:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:56
User entered 'US'	(b) (4) System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 13:48:18
User entered '5'	System	07 Apr 2021 20:20:36
User entered '4'	System	06 Apr 2021 13:01:36
User entered '3'	System	02 Apr 2021 17:01:52
User entered '2'	System	25 Mar 2021 12:16:52
User entered '1'	System	23 Mar 2021 15:19:49

**US3552010**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 08:06:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:57:33
DataPoint Verified.	(b) (4)	12 Apr 2021 16:37:20
User entered '12/Apr/2021 06:48'	(b) (4), (b) (6)	12 Apr 2021 13:48:18
	System	

US3552010

Folder: SAE USA-US089-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:06:18

**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 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:20
User entered 'l'		12 Apr 2021 13:48:18