

US3552355 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:14:39

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US3552355

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:54:57

Generated On: 10 Jun 2021 08:14:39

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Participant ID

US3552355

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

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US3552355

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552355

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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



US3552355

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Date of Informed Consent (dd MMM yyyy) 08 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3552355

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3552355

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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Were any significant conditions reported?

Yes ☒

No ☐

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US3552355

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN OCT 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552355

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN NOV 2019
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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552355

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN JUN 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552355

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

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



US3552355

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN OCT 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552355

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	RIGHT CARPAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	UN APR 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 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

US3552355

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	LEFT PERIORBITAL FRACTURE
Start date (dd MMM yyyy)	UN MAR 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	MAR 2016
Stop Year (derived)	2016

US3552355

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	CHRONIC UNUNITED FRACTURES OF PATELLA
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)	

US3552355

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 14:28:17

Generated On: 10 Jun 2021 08:14:39

Condition	CHRONIC UNUNITED FRACTURES OF PROXIMAL TIBIA
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)	

US3552355

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 08:25
Height (xxx.x)	69 in
Weight (xxx.x)	150 lb
BMI (xxx.x)	22.19744 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)	



US3552355

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3552355

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Date of assessment (*dd MMM yyyy*) 08 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN OCT 2007

Date of last menstruation unknown False

US3552355

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

GROCERY SHOPPING +  
ERRANDS 3-4X/WK

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

**No Risk Identified** False

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

US3552355

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

<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>	

US3552355

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112267

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 ☒

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Height	ND - Not Done
Weight	ND - Not Done

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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)	08 SEP 2020
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 08:25
Temperature (xxx.x)	97.3 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)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG



US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3552355

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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.*

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 09:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3552355

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

08 SEP 2020 08:55

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)			08 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	08 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3552355

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 10:02

PC Open Date & Time

08 SEP 2020 09:55

PC Close Date & Time

08 SEP 2020 12:25

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	08 SEP 2020 17:02
PC Open Date & Time	08 SEP 2020 13:20
PC Close Date & Time	09 SEP 2020 11:59



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 22:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 21:03

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 23:52

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

12 SEP 2020 22:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

13 SEP 2020 19:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 03:47

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**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

08 SEP 2020 10:03

PC Open Date & Time

08 SEP 2020 09:55

PC Close Date & Time

08 SEP 2020 12:25

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**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

08 SEP 2020 17:02

PC Open Date & Time

08 SEP 2020 13:20

PC Close Date & Time

09 SEP 2020 11:59



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**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

09 SEP 2020 20:55

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**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

10 SEP 2020 21:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**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

11 SEP 2020 23:53

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**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

12 SEP 2020 22:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**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

13 SEP 2020 19:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 03:47

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:03
PC Open Date & Time	08 SEP 2020 09:55
PC Close Date & Time	08 SEP 2020 12:25



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:03
PC Open Date & Time	08 SEP 2020 13:20
PC Close Date & Time	09 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

54 of 2709

EAB) (1725)

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:56
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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 ☒

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

58 of 2709

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 23:53
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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 ☒

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:59
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

62 of 2709

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:49
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

64 of 2709

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 03:48
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

---

**TIMEPOINT**

DAY 8

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 SEP 2020 21:52

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

---

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

---

**TIMEPOINT**

DAY 9

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 SEP 2020 21:50

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

---



US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 21:53
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 21:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3552355

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552355

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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)	05 OCT 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 11:44
Temperature (xxx.x)	97.1 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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)	05 OCT 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 13:26
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3552355

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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) 05 OCT 2020

What was the treatment time? (00:00-23:59) 12:52 (24 HR)

Treatment Date and Time (derived) 05 OCT 2020 12:52

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

US3552355

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)			05 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:30	05 OCT 2020 12:30
Nasopharyngeal Swab 2	No		

US3552355

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**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

98.9 °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

05 OCT 2020 13:27

PC Open Date & Time

05 OCT 2020 13:12

PC Close Date & Time

05 OCT 2020 15:42

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °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	05 OCT 2020 19:59
PC Open Date & Time	05 OCT 2020 16:37
PC Close Date & Time	06 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**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 98.6 °F

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

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

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

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

PC Time Stamp 06 OCT 2020 20:44

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**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

98.7 °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

08 OCT 2020 07:10

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 05:14

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

09 OCT 2020 21:21

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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 OCT 2020 04:09

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**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

98.9 °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 OCT 2020 15:17

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**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

05 OCT 2020 13:28

PC Open Date & Time

05 OCT 2020 13:12

PC Close Date & Time

05 OCT 2020 15:42

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**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

05 OCT 2020 20:00

PC Open Date & Time

05 OCT 2020 16:37

PC Close Date & Time

06 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**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

06 OCT 2020 20:45

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**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

08 OCT 2020 07:10

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**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

09 OCT 2020 05:15

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**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

09 OCT 2020 21:21

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**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

11 OCT 2020 04:10

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**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

11 OCT 2020 15:17

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 13:28
PC Open Date & Time	05 OCT 2020 13:12
PC Close Date & Time	05 OCT 2020 15:42

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 20:01
PC Open Date & Time	05 OCT 2020 16:37
PC Close Date & Time	06 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**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)

104 of 2709

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:46
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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)

106 of 2709

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

108 of 2709

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 05:16
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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)

110 of 2709

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 2709

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 04:11
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**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 ☒

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 15:17
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59



US3552355

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:55:26

Generated On: 10 Jun 2021 08:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:55:26

Generated On: 10 Jun 2021 08:14:39

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) \_\_\_\_\_



US3552355

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:55:26

Generated On: 10 Jun 2021 08:14:39

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.*

US3552355

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:55:26

Generated On: 10 Jun 2021 08:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 NOV 2020
Collection time (00:00-23:59)	10:14 (24 HR)
Collection date and time (derived)	04 NOV 2020 10:14

US3552355

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:26

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 11:32:25

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

18 NOV 2020 19:27:36

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 13:10:34
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

<b>TIMEPOINT</b>	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 07:35:00
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 09:26:49

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 10:32:32
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

20 DEC 2020 17:59:59

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 06:53:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

02 JAN 2021 18:53:59

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 22:31:32

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

<b>TIMEPOINT</b>	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 <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 JAN 2021 18:21:36
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

24 JAN 2021 17:59:53

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

31 JAN 2021 22:01:18

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

07 FEB 2021 18:10:15

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

12 FEB 2021 20:35:02

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 16:45:55
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

28 FEB 2021 07:17:30

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 MAR 2021 12:00:42

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 18:14:50

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 12:00:52

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

29 MAR 2021 02:57:38

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

04 APR 2021 07:00:17

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 20:29:08

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 09:02:46

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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

25 APR 2021 18:17:17

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 20:34:09

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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 <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"/>



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐ Yes ☐

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

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐ Yes ☐

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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20 JAN 2022 00:01

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24 JAN 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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27 JAN 2022 00:01

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31 JAN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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07 FEB 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

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Date and time of submission

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14 FEB 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



US3552355

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

**Form: Safety Follow Up Diary**

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

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21 FEB 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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Date and time of submission

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28 FEB 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

Date and time of submission

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07 MAR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

Date and time of submission

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14 MAR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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24 MAR 2022 00:01

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28 MAR 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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Date and time of submission

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07 APR 2022 00:01

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11 APR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



US3552355

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

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Date and time of submission

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18 APR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐ Yes ☐

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



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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05 SEP 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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 <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"/>

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**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 ☐

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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

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[Patient Cloud Open Date & Time](#)

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10 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 NOV 2022 23:59

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US3552355

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:14:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	28 FEB 2021 07:18:05

US3552355

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552355

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:00:26

Generated On: 10 Jun 2021 08:14:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552355

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:00:26

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

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) \_\_\_\_\_



US3552355

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

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.*

US3552355

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 APR 2021
Collection time (00:00-23:59)	10:16 (24 HR)
Collection date and time (derived)	5 APR 2021 10:16

US3552355

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552355

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

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*

**US3552355**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:14:39**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552355

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:14:39

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"/>

**US3552355**

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

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

**Generated On: 10 Jun 2021 08:14:39**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552355

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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

Visit date (dd MMM yyyy)	21 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552355

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:37:57

Generated On: 10 Jun 2021 08:14:39

Date of updated informed consent (dd MMM yyyy) 21 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) 21 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 \_\_\_\_\_

US3552355

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	08:16 (24 HR)
Collection date and time (derived)	21 JAN 2021 08:16

US3552355

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	08:20
Collection Date and Time (derived)	21 JAN 2021 08:20

US3552355

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:55:24

Generated On: 10 Jun 2021 08:14:39

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

AEID

Adverse event

GENERALIZED JOINT ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

336 of 2709

EAB) (1725)

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

AEID

Adverse event

SWOLLEN EYES

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)

06 OCT 2020

Start time (00:00-23:59)

15:00 (24 HR)

AE start date and time (derived)

06 OCT 2020 15:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 2709

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

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



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

AEID

Adverse event

DERMATITIS AROUND BASE OF  
NOSE

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)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 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 ☐

PRODUCTION RELEASE (v12.003

340 of 2709

EAB) (1725)

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

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 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)	

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

AEID	USA-US089-2021-MRNA-1273-P30 1000007
Adverse event	OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF RIGHT TIBIA
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 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	26 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

342 of 2709

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:13:15

Generated On: 10 Jun 2021 08:14:39

---

SUBJECT FELL WHILE SKIING  
AND WAS TRANSPORTED TO  
ED FOR EVALUATION. ON  
X-RAY WAS FOUND TO HAVE  
OPEN FRACTURE OF RIGHT  
FIBULA WITH DISPLACED  
FRACTURE OF TIBIA.  
INITIALLY PLACED IN  
ORTHOGLASS SPLINT IN ED,  
THEN UNDERWENT OPEN  
REDUCTION INTERNAL  
FIXATION PROCEDURE ON 3/25.  
COVID TESTING NEGATIVE  
DURING HOSPITAL STAY FROM  
3/25-3/26, WAS KEPT  
OVERNIGHT FOR  
OBSERVATION. WILL SEND  
RECORDS TO MEDICAL  
MONITOR.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:55:25

Generated On: 10 Jun 2021 08:14:39

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

Yes ☒

No ☐

---

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

---

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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)

346 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 JUN 2002	
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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication CHLORTHALIDONE

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)

348 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 OCT 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

350 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 OCT 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication VYVANSE

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT DISORDER

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)

352 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 NOV 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication VENLAFAXINE

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 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 MAR 2009	
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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication HEALTH

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)

356 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 JUN 2002	
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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication FISH OIL

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

3X/WEEK

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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)

360 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 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 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL  
ALLERGIES/HEADACHE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

362 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)		21 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)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication CLOBETASOL

Prophylaxis Yes ☐  
No ☒

Indication PSORIATIC ARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 TWO WEEKS ON THEN TWO WEEKS OFF

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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)

366 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 OCT 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication SWOLLEN EYES

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)

368 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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 INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	26 OCT 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication DERMATITIS AROUND BASE OF NOSE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)	24 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)		10 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication DERMAL FILLER

Prophylaxis Yes ☐  
No ☒

Indication POST LEFT PERIORBITAL FRACTURE

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 TWICE A YEAR

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

376 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)	25 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 APR 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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)		25 MAR 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication SENNA

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication DEXMEDETOMIDINE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 75

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)

392 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

398 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

400 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication LIDOCAINE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

402 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 2

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)

404 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 2

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)

406 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 2

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)

408 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

410 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

412 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

Dose per administration 140

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)

414 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication ROCURONIUM

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication OPEN REDUCTION INTERNAL  
FIXATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

418 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 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)		25 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"/>



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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)

420 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

	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"/>

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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)

422 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

Name of Medication ALIGN [BIFIDOBACTERIUM  
LONGUM]

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

424 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 15:30:56

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:13:16

Generated On: 10 Jun 2021 08:14:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 MAR 2021	OPEN REDUCTION INTERNAL FIXATION	Adverse Event	



US3552355

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:14:39

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

US3552355

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:14:39

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 ☐

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

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

Generated On: 10 Jun 2021 08:14:39

SAEID	USA-US089-2021-MRNA-1273-P301000007
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)	4

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

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

Generated On: 10 Jun 2021 08:14:39

SAEID	USA-US089-2021-MRNA-1273-P301000007
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)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 13:54
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

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

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

Generated On: 10 Jun 2021 08:14:39

SAEID	USA-US089-2021-MRNA-1273-P301000007
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)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 15:25
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

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

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

Generated On: 10 Jun 2021 08:14:39

SAEID	USA-US089-2021-MRNA-1273-P301000007
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)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 13:24
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

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

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

Generated On: 10 Jun 2021 08:14:39

SAEID	USA-US089-2021-MRNA-1273-P301000007
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)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 13:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3552355 (Prod: Saint Louis University)



US3552355

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:14:39**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:49:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
User entered 'US3552355'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:44:45

US3552355

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:10:49
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:33:59

US3552355

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:10:49
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:44:46

US3552355

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:10:49
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:33:59

US3552355

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'SCRN'	System	08 Sep 2020 15:33:59

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:44:47

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '53'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'YEARS'	System	08 Sep 2020 15:34:15



US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '53'	System	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered 'Female (F)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4)	08 Sep 2020 15:34:15
	(b) (4)	

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:12:42
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 13:12:42
	Mikayla Frye (b) (4)	08 Sep 2020 15:34:15
	(b) (4)	

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15



US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:14:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:42
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:15

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:28:59
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:28:59
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:00
	(b) (4)	10 Nov 2020 20:43:00
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:00
	(b) (4)	10 Nov 2020 20:43:00
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:49
User entered '8 Sep 2020'		08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Sep 2020'	System	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2020'	System	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:49
User entered 'Amendment 3 (3)'		08 Sep 2020 14:08:25



US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:49
User entered 'Yes (Y)'		08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:12:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:12:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:12:49
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:08:25

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:12:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:44:46

US3552355

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:14:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'l'	System	08 Sep 2020 14:08:31

US3552355

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:13:20
User entered 'Yes (Y)'		08 Sep 2020 14:08:31

US3552355

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:14:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:13:38
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:21



US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:35:51
Data point term sent to Coder	System	08 Sep 2020 15:34:47
User entered 'hypertension'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Oct 2016'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Oct 2016'	System	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2016'	System	08 Sep 2020 15:34:42



US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:34:42

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:36:54
Data point term sent to Coder	System	08 Sep 2020 15:35:49
User entered 'attention deficit disorder'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Nov 2019'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:34:54



US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Nov 2019'	System	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2019'	System	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:34:54

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Psoriatic arthropathies, PT: Psoriatic arthropathy, LLT: Psoriatic arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:36:55
Data point term sent to Coder	System	08 Sep 2020 15:35:51
User entered 'psoriatic arthritis'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Feb 2020'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:30



US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Feb 2020'	System	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2020'	System	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:30

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
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)	08 Sep 2020 15:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:36:55
Data point term sent to Coder	System	08 Sep 2020 15:35:53
User entered 'hypercholesterolemia'	Mikayla Frye (b) (4)	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:14:32
User entered 'un Jun 2002'	(b) (4), (b) (6)	15 Sep 2020 13:14:32
	Mikayla Frye (b) (4)	08 Sep 2020 15:35:44
	(b) (4)	



US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Jun 2002'	System	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2002'	System	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:44

US3552355

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:44



US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:37:51
Data point term sent to Coder	System	08 Sep 2020 15:36:55
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Mar 2009'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:35:57
	(b) (4)	

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Mar 2009'	System	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2009'	System	08 Sep 2020 15:35:57



US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:35:57

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:39:49
Data point term sent to Coder	System	08 Sep 2020 15:39:01
User entered 'uterine ablation'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Oct 2007'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Oct 2007'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:03



US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Oct 2007'	System	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2007'	System	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Oct 2007'	System	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2007'	System	08 Sep 2020 15:38:03

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
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)	08 Sep 2020 15:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:39:49
Data point term sent to Coder	System	08 Sep 2020 15:39:03
User entered 'seasonal allergies'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Oct 2016'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:17



US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:14:32
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
	Mikayla Frye (b) (4)	08 Sep 2020 15:38:17
	(b) (4)	

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Oct 2016'	System	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2016'	System	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:38:17

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:39:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:39:50
Data point term sent to Coder	System	08 Sep 2020 15:39:04
User entered 'right carpal tunnel syndrome'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Apr 2020'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45



US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Apr 2020'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Apr 2020'	System	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2020'	System	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Apr 2020'	System	08 Sep 2020 15:38:45

US3552355

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2020'	System	08 Sep 2020 15:38:45



US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:14:32
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:40:50
Data point term sent to Coder	System	08 Sep 2020 15:40:06
User entered 'post-menopausal'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'un Oct 2007'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:14:32
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Oct 2007'	System	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2007'	System	08 Sep 2020 15:39:05



US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	08 Sep 2020 15:39:05

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Orbital fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Mar 2021 07:37:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 07:37:59
Data point term sent to Coder	System	18 Mar 2021 20:24:06
User entered 'left periorbital fracture'	Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'un Mar 2016'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'un Mar 2016'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		30 Mar 2021 15:17:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered '0'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	18 Mar 2021 20:23:27



US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Mar 2016'	System	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2016'	System	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'Mar 2016'	System	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '2016'	System	18 Mar 2021 20:23:27

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Patella fracture, LLT: Fracture of patella - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 20:14:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:14:41
Data point term sent to Coder	System	06 Apr 2021 18:25:10
User entered 'chronic ununited fractures of patella'	Heather Douds (b) (4)	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:37



US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:21
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:37

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Tibia fracture, LLT: Tibia fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 20:14:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:14:51
Data point term sent to Coder	System	06 Apr 2021 18:25:09
User entered 'chronic ununited fractures of proximal tibia'	Heather Douds (b) (4)	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:56



US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
DataPoint Verified.		09 Apr 2021 16:32:23
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:56

US3552355

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:14:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered empty.	System	06 Apr 2021 18:24:56



US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:29:11
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:29:11
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:16
	(b) (4)	10 Nov 2020 20:43:16
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:39:57
	(b) (4)	

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered '08:25'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '08 Sep 2020 08:25'	System	10 Nov 2020 20:43:16
User entered '8 Sep 2020 08:25'	System	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered '69' in	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57
DataPoint set to visible.	System	08 Sep 2020 14:08:31

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered '150' lb	Mikayla Frye (b) (4)	08 Sep 2020 15:39:57
	(b) (4)	
DataPoint set to visible.	System	08 Sep 2020 14:08:31

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered '22.19744'	System	08 Sep 2020 15:39:57
DataPoint set to visible.	System	08 Sep 2020 14:08:31

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'kg/m2'	System	08 Sep 2020 15:39:57
DataPoint set to visible.	System	08 Sep 2020 14:08:31



US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'bpm'	System	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'breaths/min'	System	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57



US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'mmHg'	System	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:05
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User entered 'mmHg'	System	08 Sep 2020 15:39:57

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34

US3552355

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34

US3552355

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 13:17:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	08 Sep 2020 15:40:07
	(b) (4)	

US3552355

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:29:22
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:29:22
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:21
	(b) (4)	10 Nov 2020 20:43:21
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:21
	(b) (4)	10 Nov 2020 20:43:21
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:12
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:40:07
	(b) (4)	08 Sep 2020 15:40:07

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 01:18:35
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 20:43:25
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:25
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:39:25



US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered 'UN Oct 2007'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:14:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:17:18
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:39:25

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57



US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57



US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered 'grocery shopping + errands 3-4x/wk'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered '0'	Mikayla Frye (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

**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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[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 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57



US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

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 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:29:48
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 13:29:48
	Mikayla Frye (b) (4)	08 Sep 2020 15:40:57
	(b) (4)	

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:29:48
User entered 'l'	(b) (4), (b) (6)	15 Sep 2020 13:29:48
	Mikayla Frye (b) (4)	08 Sep 2020 15:40:57
	(b) (4)	

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:14:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:29:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:40:57

US3552355

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:01
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:06

US3552355

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:29:50
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:29:50
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:45
	(b) (4)	10 Nov 2020 20:43:45
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:01
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:41:06
	(b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:01
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:06

US3552355

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'VISIT1'	System	08 Sep 2020 15:41:06



US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:30:15
User entered '08 SEP 2020'	(b) (4), (b) (6)	15 Sep 2020 13:30:15
	RWS_ENDPOINT	08 Sep 2020 14:09:46
	ENDPOINT (b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:30:15
User entered '112267'	(b) (4), (b) (6)	15 Sep 2020 13:30:15
	RWS_ENDPOINT	08 Sep 2020 14:09:46
	ENDPOINT (b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:30:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4), (b) (6)	15 Sep 2020 13:30:15
	RWS_ENDPOINT	08 Sep 2020 14:09:46
	ENDPOINT (b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:18

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:18

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:18

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:18

US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:30:15
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:41:18



US3552355

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:14:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	28 Oct 2020 20:05:00
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:05:00
	Stanley Doublin (b) (4)	21 Sep 2020 17:59:59
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:36:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:36:36

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:04
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:04
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:55
	(b) (4)	10 Nov 2020 20:43:55
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:55
	(b) (4)	10 Nov 2020 20:43:55
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:42:18
	(b) (4)	08 Sep 2020 15:42:18



US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '08:25'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '08 Sep 2020 08:25'	System	10 Nov 2020 20:43:55
User entered '8 Sep 2020 08:25'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '97.3' F	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '80'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'bpm'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '16'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18



US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'breaths/min'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '121'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 10:02:27
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS; not an AE' (Site from System).	Joan Siegner (b) (4) (b) (4)	23 Sep 2020 16:20:04
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:57
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '57'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18



US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:08
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:08
	Mikayla Frye (b) (4)	10 Nov 2020 20:43:55
	(b) (4)	10 Nov 2020 20:43:55
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:43:55
	(b) (4)	10 Nov 2020 20:43:55
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:42:18
	(b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '10:05'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '08 Sep 2020 10:05'	System	10 Nov 2020 20:43:55
User entered '8 Sep 2020 10:05'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '97.9' F	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '86'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18



US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'bpm'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '19'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'breaths/min'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '102'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 10:02:44
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS; not an AE' (Site from System).	Joan Siegner (b) (4)	23 Sep 2020 16:20:17
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:57
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:38
User entered '59'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	08 Sep 2020 15:42:18

US3552355

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:47
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:25



US3552355

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:47
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:25

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:31:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:31:56
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:31:56
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:21
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:21
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:03
	(b) (4)	10 Nov 2020 20:44:03
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:56
User entered '8 Sep 2020'		08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:31:56
User entered '09:35'		08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered '08 Sep 2020 09:35'	System	10 Nov 2020 20:44:03
User entered '8 Sep 2020 09:35'	System	08 Sep 2020 14:41:47



US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:31:56
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
DataPoint Verified.		15 Sep 2020 13:31:56
User entered 'ONCE'	System	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:41:47

US3552355

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:03
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:37

US3552355

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:28
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:08
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:03
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:42:37
	(b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:03
User entered '08:55'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:37

US3552355

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered '08 Sep 2020 08:55'	System	10 Nov 2020 20:44:08
User entered '8 Sep 2020 08:55'	System	08 Sep 2020 15:42:37

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:36
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:36
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:17
	(b) (4)	10 Nov 2020 20:44:17
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:17
	(b) (4)	10 Nov 2020 20:44:17
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:09
User entered '8 Sep 2020'	Mikayla Frye (b) (4)	08 Sep 2020 15:42:48
	(b) (4)	08 Sep 2020 15:42:48



US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:09
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:09
User entered '09:00'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered '08 Sep 2020 09:00'	System	10 Nov 2020 20:44:17
User entered '8 Sep 2020 09:00'	System	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 13:32:09
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:42:48

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Sep 2020 13:32:09
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 13:32:09
	Mikayla Frye (b) (4)	08 Sep 2020 15:42:48
	(b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered empty.	System	08 Sep 2020 15:42:48



US3552355

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:06:43
	Stanley Doublin (b) (4)	15 Sep 2020 17:56:51
	(b) (4)	

US3552355

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'I'	System	15 Sep 2020 17:56:51

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:02:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e4baf18f-c1c1-41bf-bf65-1dba1eda6438' User entered 'Yes (Y)'	System	08 Sep 2020 15:02:50
	System	08 Sep 2020 15:02:50

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:02:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e4baf18f-c1c1-41bf-bf65-1dba1eda6438' User entered '97.9'	System	08 Sep 2020 15:02:50
	System	08 Sep 2020 15:02:50

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:02:41', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e4baf18f-c1c1-41bf-bf65-1dba1eda6438'	System	08 Sep 2020 15:02:50
User entered 'No (N)'	System	08 Sep 2020 15:02:50

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:02:47', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e4baf18f-c1c1-41bf-bf65-1dba1eda6438' User entered '08 Sep 2020 10:02'	System	08 Sep 2020 15:02:50
	System	08 Sep 2020 15:02:50

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 09:55'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:01:24', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9cacf63c-efc3-4181-b71d-291459c79f9a' User entered 'Yes (Y)'	System	08 Sep 2020 22:02:17
	System	08 Sep 2020 22:02:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:01:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9cacf63c-efc3-4181-b71d-291459c79f9a' User entered '97.5'	System	08 Sep 2020 22:02:17
	System	08 Sep 2020 22:02:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:01:35', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9cacf63c-efc3-4181-b71d-291459c79f9a'	System	08 Sep 2020 22:02:17
User entered 'No (N)'	System	08 Sep 2020 22:02:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9cacf63c-efc3-4181-b71d-291459c79f9a' User entered '08 Sep 2020 17:02'	System	08 Sep 2020 22:02:17
	System	08 Sep 2020 22:02:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 13:20'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 2'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T22:17:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f36c936c-778f-4964-bf49-4f0267617792'	System	10 Sep 2020 03:18:00
User entered 'Yes (Y)'	System	10 Sep 2020 03:18:00

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T22:17:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f36c936c-778f-4964-bf49-4f0267617792'	System	10 Sep 2020 03:18:00
User entered '97.8'	System	10 Sep 2020 03:18:00

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T22:17:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f36c936c-778f-4964-bf49-4f0267617792'	System	10 Sep 2020 03:18:00
User entered 'No (N)'	System	10 Sep 2020 03:18:00

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T22:17:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f36c936c-778f-4964-bf49-4f0267617792'	System	10 Sep 2020 03:18:00
User entered '09 Sep 2020 22:17'	System	10 Sep 2020 03:18:00

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 3'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:03:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '191b6e63-15af-4b35-86c4-0dea56794cf2'	System	11 Sep 2020 02:03:23
User entered 'Yes (Y)'	System	11 Sep 2020 02:03:23

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:03:09', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '191b6e63-15af-4b35-86c4-0dea56794cf2' User entered '97.8'	System	11 Sep 2020 02:03:23
	System	11 Sep 2020 02:03:23

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:03:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '191b6e63-15af-4b35-86c4-0dea56794cf2'	System	11 Sep 2020 02:03:23
User entered 'No (N)'	System	11 Sep 2020 02:03:23

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:03:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '191b6e63-15af-4b35-86c4-0dea56794cf2' User entered '10 Sep 2020 21:03'	System	11 Sep 2020 02:03:23
	System	11 Sep 2020 02:03:23

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 4'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:52:40', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '38d90a70-d5d1-4c95-8f1b-023dde8b0cec' User entered 'Yes (Y)'	System	12 Sep 2020 04:52:56
	System	12 Sep 2020 04:52:56



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:52:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '38d90a70-d5d1-4c95-8f1b-023dde8b0cec' User entered '97.5'	System	12 Sep 2020 04:52:56
	System	12 Sep 2020 04:52:56

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:52:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '38d90a70-d5d1-4c95-8f1b-023dde8b0cec' User entered 'No (N)'	System	12 Sep 2020 04:52:56
	System	12 Sep 2020 04:52:56

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:52:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '38d90a70-d5d1-4c95-8f1b-023dde8b0cec' User entered '11 Sep 2020 23:52'	System	12 Sep 2020 04:52:56
	System	12 Sep 2020 04:52:56

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 5'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e46867a7-39b0-4669-939e-3cfd476243b0' User entered 'Yes (Y)'	System	13 Sep 2020 03:58:52
	System	13 Sep 2020 03:58:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:17', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e46867a7-39b0-4669-939e-3cfd476243b0' User entered '98.3'	System	13 Sep 2020 03:58:52
	System	13 Sep 2020 03:58:52



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e46867a7-39b0-4669-939e-3cfd476243b0' User entered 'No (N)'	System	13 Sep 2020 03:58:52
	System	13 Sep 2020 03:58:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:23', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e46867a7-39b0-4669-939e-3cfd476243b0' User entered '12 Sep 2020 22:58'	System	13 Sep 2020 03:58:52
	System	13 Sep 2020 03:58:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 6'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c417f396-f458-4013-a8a7-68a7ae9a22e5' User entered 'Yes (Y)'	System	14 Sep 2020 00:48:52
	System	14 Sep 2020 00:48:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:39', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c417f396-f458-4013-a8a7-68a7ae9a22e5' User entered '98.6'	System	14 Sep 2020 00:48:52
	System	14 Sep 2020 00:48:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:42', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c417f396-f458-4013-a8a7-68a7ae9a22e5' User entered 'No (N)'	System	14 Sep 2020 00:48:52
	System	14 Sep 2020 00:48:52



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c417f396-f458-4013-a8a7-68a7ae9a22e5'	System	14 Sep 2020 00:48:52
User entered '13 Sep 2020 19:48'	System	14 Sep 2020 00:48:52

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 7'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:46:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cfa532f2-05c9-4564-b5e9-67edb2fb8b20' User entered 'Yes (Y)'	System	15 Sep 2020 08:47:17
	System	15 Sep 2020 08:47:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cfa532f2-05c9-4564-b5e9-67edb2fb8b20' User entered '98.5'	System	15 Sep 2020 08:47:17
	System	15 Sep 2020 08:47:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cfa532f2-05c9-4564-b5e9-67edb2fb8b20'	System	15 Sep 2020 08:47:17
User entered 'No (N)'	System	15 Sep 2020 08:47:17

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cfa532f2-05c9-4564-b5e9-67edb2fb8b20' User entered '15 Sep 2020 03:47'	System	15 Sep 2020 08:47:17
	System	15 Sep 2020 08:47:17



US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:02:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99d99c53-60be-400d-9f59-06978dc37225'	System	08 Sep 2020 15:03:12
User entered 'None (1)'	System	08 Sep 2020 15:03:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99d99c53-60be-400d-9f59-06978dc37225'	System	08 Sep 2020 15:03:12
User entered 'No (N)'	System	08 Sep 2020 15:03:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:03', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99d99c53-60be-400d-9f59-06978dc37225'	System	08 Sep 2020 15:03:12
User entered 'No (N)'	System	08 Sep 2020 15:03:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:06', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99d99c53-60be-400d-9f59-06978dc37225'	System	08 Sep 2020 15:03:12
User entered 'None (1)'	System	08 Sep 2020 15:03:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:09', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99d99c53-60be-400d-9f59-06978dc37225' User entered '08 Sep 2020 10:03'	System	08 Sep 2020 15:03:12
	System	08 Sep 2020 15:03:12



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 09:55'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6c55aebb-4fca-45c6-8d03-2ccae1e410d9'	System	08 Sep 2020 22:02:54
User entered 'None (1)'	System	08 Sep 2020 22:02:54

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:37', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6c55aebb-4fca-45c6-8d03-2ccae1e410d9' User entered 'No (N)'	System	08 Sep 2020 22:02:54
	System	08 Sep 2020 22:02:54

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6c55aebb-4fca-45c6-8d03-2ccae1e410d9' User entered 'No (N)'	System	08 Sep 2020 22:02:54
	System	08 Sep 2020 22:02:54

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6c55aebb-4fca-45c6-8d03-2ccae1e410d9'	System	08 Sep 2020 22:02:54
User entered 'None (1)'	System	08 Sep 2020 22:02:54

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:02:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6c55aebb-4fca-45c6-8d03-2ccae1e410d9' User entered '08 Sep 2020 17:02'	System	08 Sep 2020 22:02:54
	System	08 Sep 2020 22:02:54



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 13:20'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 2'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2a828d08-c726-4d15-96c9-ee069feb66c9'	System	10 Sep 2020 01:55:37
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 01:55:37

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:17', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2a828d08-c726-4d15-96c9-ee069feb66c9' User entered 'No (N)'	System	10 Sep 2020 01:55:37
	System	10 Sep 2020 01:55:37

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2a828d08-c726-4d15-96c9-ee069feb66c9' User entered 'No (N)'	System	10 Sep 2020 01:55:37
	System	10 Sep 2020 01:55:37

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2a828d08-c726-4d15-96c9-ee069feb66c9'	System	10 Sep 2020 01:55:37
User entered 'None (1)'	System	10 Sep 2020 01:55:37

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2a828d08-c726-4d15-96c9-ee069feb66c9' User entered '09 Sep 2020 20:55'	System	10 Sep 2020 01:55:37
	System	10 Sep 2020 01:55:37



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 3'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:08', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4ba4bd47-128a-4697-8431-c1c3c3c113d9' User entered 'None (1)'	System	11 Sep 2020 02:02:23
	System	11 Sep 2020 02:02:23

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4ba4bd47-128a-4697-8431-c1c3c3c113d9' User entered 'No (N)'	System	11 Sep 2020 02:02:23
	System	11 Sep 2020 02:02:23

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4ba4bd47-128a-4697-8431-c1c3c3c113d9' User entered 'No (N)'	System	11 Sep 2020 02:02:23
	System	11 Sep 2020 02:02:23

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4ba4bd47-128a-4697-8431-c1c3c3c113d9' User entered 'None (1)'	System	11 Sep 2020 02:02:23
	System	11 Sep 2020 02:02:23

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:21', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4ba4bd47-128a-4697-8431-c1c3c3c113d9' User entered '10 Sep 2020 21:02'	System	11 Sep 2020 02:02:23
	System	11 Sep 2020 02:02:23



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 4'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:52:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'd35789e5-3bee-45d8-a360-8fba36f9e10a'	System	12 Sep 2020 04:53:12
User entered 'None (1)'	System	12 Sep 2020 04:53:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'd35789e5-3bee-45d8-a360-8fba36f9e10a' User entered 'No (N)'	System	12 Sep 2020 04:53:12
	System	12 Sep 2020 04:53:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:04', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'd35789e5-3bee-45d8-a360-8fba36f9e10a' User entered 'No (N)'	System	12 Sep 2020 04:53:12
	System	12 Sep 2020 04:53:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:07', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'd35789e5-3bee-45d8-a360-8fba36f9e10a' User entered 'None (1)'	System	12 Sep 2020 04:53:12
	System	12 Sep 2020 04:53:12

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:10', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'd35789e5-3bee-45d8-a360-8fba36f9e10a' User entered '11 Sep 2020 23:53'	System	12 Sep 2020 04:53:12
	System	12 Sep 2020 04:53:12



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 5'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5ed4f7b0-6391-44a7-b687-fc90c8d86ce7' User entered 'None (1)'	System	13 Sep 2020 03:58:55
	System	13 Sep 2020 03:58:55

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5ed4f7b0-6391-44a7-b687-fc90c8d86ce7' User entered 'No (N)'	System	13 Sep 2020 03:58:55
	System	13 Sep 2020 03:58:55

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:33', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5ed4f7b0-6391-44a7-b687-fc90c8d86ce7' User entered 'No (N)'	System	13 Sep 2020 03:58:55
	System	13 Sep 2020 03:58:55

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5ed4f7b0-6391-44a7-b687-fc90c8d86ce7' User entered 'None (1)'	System	13 Sep 2020 03:58:55
	System	13 Sep 2020 03:58:55

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:39', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5ed4f7b0-6391-44a7-b687-fc90c8d86ce7' User entered '12 Sep 2020 22:58'	System	13 Sep 2020 03:58:55
	System	13 Sep 2020 03:58:55



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 6'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:51', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b55b1dd5-bd74-41dd-8b32-0e4df5ef2747'	System	14 Sep 2020 00:49:07
User entered 'None (1)'	System	14 Sep 2020 00:49:07

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b55b1dd5-bd74-41dd-8b32-0e4df5ef2747'	System	14 Sep 2020 00:49:07
User entered 'No (N)'	System	14 Sep 2020 00:49:07

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:48:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b55b1dd5-bd74-41dd-8b32-0e4df5ef2747' User entered 'No (N)'	System	14 Sep 2020 00:49:07
	System	14 Sep 2020 00:49:07

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b55b1dd5-bd74-41dd-8b32-0e4df5ef2747' User entered 'None (1)'	System	14 Sep 2020 00:49:07
	System	14 Sep 2020 00:49:07

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:03', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b55b1dd5-bd74-41dd-8b32-0e4df5ef2747' User entered '13 Sep 2020 19:49'	System	14 Sep 2020 00:49:07
	System	14 Sep 2020 00:49:07



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 7'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:19', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e0be33a8-b1b1-48c6-87d1-b0a963cc8f99'	System	15 Sep 2020 08:47:39
User entered 'None (1)'	System	15 Sep 2020 08:47:39

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:24', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e0be33a8-b1b1-48c6-87d1-b0a963cc8f99'	System	15 Sep 2020 08:47:39
User entered 'No (N)'	System	15 Sep 2020 08:47:39

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:28', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e0be33a8-b1b1-48c6-87d1-b0a963cc8f99'	System	15 Sep 2020 08:47:39
User entered 'No (N)'	System	15 Sep 2020 08:47:39

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e0be33a8-b1b1-48c6-87d1-b0a963cc8f99'	System	15 Sep 2020 08:47:39
User entered 'None (1)'	System	15 Sep 2020 08:47:39

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:37', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e0be33a8-b1b1-48c6-87d1-b0a963cc8f99'	System	15 Sep 2020 08:47:39
User entered '15 Sep 2020 03:47'	System	15 Sep 2020 08:47:39



US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:23', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:24', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered 'None (0)'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:35', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135'	System	08 Sep 2020 15:03:42
User entered 'No (N)'	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T10:03:38', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a4fc157c-073f-41a4-8a34-e0831c3c8135' User entered '08 Sep 2020 10:03'	System	08 Sep 2020 15:03:42
	System	08 Sep 2020 15:03:42

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 09:55'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:07', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'No interference with activity (1)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'None (0)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'None (0)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'None (0)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:23', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'None (0)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'None (0)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered 'No (N)'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-08T17:03:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ba8fd64-b14b-44f3-b701-8748ddf174cf' User entered '08 Sep 2020 17:03'	System	08 Sep 2020 22:03:39
	System	08 Sep 2020 22:03:39

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Sep 2020 13:20'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 2'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:41', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:51', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:55:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:56:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:56:03', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:56:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'None (0)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:56:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered 'No (N)'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-09T20:56:17', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '80c0545d-42b2-4aee-afdb-f947d5806ebd' User entered '09 Sep 2020 20:56'	System	10 Sep 2020 01:56:20
	System	10 Sep 2020 01:56:20

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 3'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'None (0)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:29', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'None (0)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'None (0)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:40', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6'	System	11 Sep 2020 02:02:56
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:02:56



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'None (0)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'None (0)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered 'No (N)'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-10T21:02:53', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a92505e3-1fe9-434b-8435-05f5a58209f6' User entered '10 Sep 2020 21:02'	System	11 Sep 2020 02:02:56
	System	11 Sep 2020 02:02:56

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 4'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:16', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bf9-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bfb-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:23', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bfb-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bfb-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:28', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bf9-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bf9-95a7-412e-ab1e-6a3376dbb74c' User entered 'None (0)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bfb-95a7-412e-ab1e-6a3376dbb74c' User entered 'No (N)'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-11T23:53:38', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2b4a9bfb-95a7-412e-ab1e-6a3376dbb74c' User entered '11 Sep 2020 23:53'	System	12 Sep 2020 04:53:40
	System	12 Sep 2020 04:53:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 5'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:44', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555' User entered 'None (0)'	System	13 Sep 2020 03:59:13
	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555' User entered 'None (0)'	System	13 Sep 2020 03:59:13
	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555'	System	13 Sep 2020 03:59:13
User entered 'None (0)'	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:58:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555'	System	13 Sep 2020 03:59:13
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:59:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555' User entered 'None (0)'	System	13 Sep 2020 03:59:13
	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:59:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555'	System	13 Sep 2020 03:59:13
User entered 'None (0)'	System	13 Sep 2020 03:59:13



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:59:06', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555'	System	13 Sep 2020 03:59:13
User entered 'No (N)'	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-12T22:59:08', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b0dd2574-fb7e-41a6-9e54-7fec716f3555'	System	13 Sep 2020 03:59:13
User entered '12 Sep 2020 22:59'	System	13 Sep 2020 03:59:13

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 6'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:10', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:13', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:21', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:28', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'None (0)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered 'No (N)'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-13T19:49:37', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '47deb50e-e096-458c-8d75-a4154ff0dfdd' User entered '13 Sep 2020 19:49'	System	14 Sep 2020 00:49:40
	System	14 Sep 2020 00:49:40

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 7'	System	08 Sep 2020 14:41:47



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'None (0)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:48', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'None (0)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'None (0)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:47:58', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'No interference with activity (1)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:48:07', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'None (0)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:48:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'None (0)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:48:16', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered 'No (N)'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T03:48:21', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0ad374dd-26e0-4c70-8197-a66a9c151b7e' User entered '15 Sep 2020 03:48'	System	15 Sep 2020 08:48:24
	System	15 Sep 2020 08:48:24



US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	15 Sep 2020 08:48:24
User entered 'Day 8'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T21:52:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '7e943017-085d-4729-9cad-c1f700f8b741'	System	16 Sep 2020 02:52:59
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:52:59

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T21:52:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '7e943017-085d-4729-9cad-c1f700f8b741' User entered '15 Sep 2020 21:52'	System	16 Sep 2020 02:52:59
	System	16 Sep 2020 02:52:59

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	15 Sep 2020 08:48:24
User entered 'Day 9'	System	15 Sep 2020 08:48:24



US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-16T21:50:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '28cc3f1b-4f29-43c0-8510-b22b54d8d89e' User entered 'None (0)'	System	23 Sep 2020 01:44:56
	System	23 Sep 2020 01:44:56

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-16T21:50:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '28cc3f1b-4f29-43c0-8510-b22b54d8d89e' User entered '16 Sep 2020 21:50'	System	23 Sep 2020 01:44:56
	System	23 Sep 2020 01:44:56

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	15 Sep 2020 08:48:24
User entered 'Day 8'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T21:53:01', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f04941ab-ca89-4cef-b084-fbd5665fe990' User entered 'No (N)'	System	16 Sep 2020 02:53:07
	System	16 Sep 2020 02:53:07

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-15T21:53:04', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f04941ab-ca89-4cef-b084-fbd5665fe990' User entered '15 Sep 2020 21:53'	System	16 Sep 2020 02:53:07
	System	16 Sep 2020 02:53:07

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 08:48:24



US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	15 Sep 2020 08:48:24
User entered 'Day 9'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-16T21:50:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e8385e0f-83d4-44dc-a7f6-5271cce5cca0' User entered 'No (N)'	System	23 Sep 2020 01:44:55
	System	23 Sep 2020 01:44:55

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-09-16T21:50:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e8385e0f-83d4-44dc-a7f6-5271cce5cca0' User entered '16 Sep 2020 21:50'	System	23 Sep 2020 01:44:55
	System	23 Sep 2020 01:44:55

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 08:48:24

US3552355

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 08:48:24

US3552355

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:57:00

US3552355

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:08
User entered '15 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:57:00



US3552355

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:08
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	15 Sep 2020 17:57:00

US3552355

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:07:08
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:57:00
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552355

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:14
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:54:06

US3552355

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	23 Sep 2020 14:54:06

US3552355

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:54:17

US3552355

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:21
User entered '22 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 14:54:17

US3552355

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:21
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:54:17

US3552355

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:21
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:54:17



US3552355

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 14:15:22
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:01:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:00:56

US3552355

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	30 Sep 2020 14:15:22
User entered empty.	System	23 Sep 2020 15:01:08
User entered 'l'	System	23 Sep 2020 15:00:56

US3552355

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 14:15:46

US3552355

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:35
User entered '30 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 14:15:46

US3552355

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 14:15:46

US3552355

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:35
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Sep 2020 14:15:46

US3552355

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:07:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:56:01

US3552355

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	05 Oct 2020 17:56:01



US3552355

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:42:54

US3552355

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:18:44
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 20:44:33
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data	Mikayla Frye (b) (4)	10 Nov 2020 20:44:33
Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:51
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:42:54
	(b) (4)	

US3552355

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:07:51
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:42:54

US3552355

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'VISIT2'	System	05 Oct 2020 19:42:54

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:18:51
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:18:51
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:41
	(b) (4)	10 Nov 2020 20:44:41
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:41
	(b) (4)	10 Nov 2020 20:44:41
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:43:22
	(b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '11:44'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22



US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '05 Oct 2020 11:44'	System	10 Nov 2020 20:44:41
User entered '5 Oct 2020 11:44'	System	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '97.1' F	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '80'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'bpm'	System	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '14'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'breaths/min'	System	05 Oct 2020 19:43:22



US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '137'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '73'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	05 Oct 2020 19:43:22

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:18:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:18:55
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:41
	(b) (4)	10 Nov 2020 20:44:41
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:41
	(b) (4)	10 Nov 2020 20:44:41
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:43:48
	(b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '13:26'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48



US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '05 Oct 2020 13:26'	System	10 Nov 2020 20:44:41
User entered '5 Oct 2020 13:26'	System	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '98.9' F	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered empty.	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '67'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'bpm'	System	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '12'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'breaths/min'	System	05 Oct 2020 19:43:48



US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '132'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:37
User entered '62'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'mmHg'	System	05 Oct 2020 19:43:48

US3552355

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:43:56

US3552355

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:19:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:19:01
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:45
	(b) (4)	10 Nov 2020 20:44:45
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:45
	(b) (4)	10 Nov 2020 20:44:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:45
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:43:56
	(b) (4)	05 Oct 2020 19:43:56

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:18:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:18:53
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:56:21



US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:18:53
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:19:06
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:19:06
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:51
	(b) (4)	10 Nov 2020 20:44:51
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:51
	(b) (4)	10 Nov 2020 20:44:51
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:18:53
User entered '5 Oct 2020'		05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:18:53
User entered '12:52'	(b) (4), (b) (6)	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '05 Oct 2020 12:52'	System	10 Nov 2020 20:44:51
User entered '5 Oct 2020 12:52'	System	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	15 Oct 2020 18:18:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
DataPoint Verified.		15 Oct 2020 18:18:53
User entered 'ONCE'	System	05 Oct 2020 17:56:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:14:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 17:56:21



US3552355

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:01
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:44:06

US3552355

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:19:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:19:10
	Mikayla Frye (b) (4)	10 Nov 2020 20:44:55
	(b) (4)	10 Nov 2020 20:44:55
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:44:55
	(b) (4)	10 Nov 2020 20:44:55
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:01
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:44:06
	(b) (4)	05 Oct 2020 19:44:06

US3552355

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:01
User entered '12:24'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:44:06

US3552355

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '05 Oct 2020 12:24'	System	10 Nov 2020 20:44:55
User entered '5 Oct 2020 12:24'	System	05 Oct 2020 19:44:06

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:19:15
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:19:15
	Mikayla Frye (b) (4)	10 Nov 2020 20:45:01
	(b) (4)	10 Nov 2020 20:45:01
User entered '05 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:45:01
	(b) (4)	10 Nov 2020 20:45:01
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:07
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 19:44:21
	(b) (4)	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 18:19:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	05 Oct 2020 19:44:21
	(b) (4)	

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:07
User entered '12:30'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:44:21



US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:14:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '05 Oct 2020 12:30'	System	10 Nov 2020 20:45:01
User entered '5 Oct 2020 12:30'	System	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:07
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:14:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	05 Oct 2020 19:44:21

US3552355

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 14:44:00

US3552355

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'l'	System	13 Oct 2020 14:44:00

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '575eba54-5144-425e-8ec7-e42b1ff3d4ff' User entered 'Yes (Y)'	System	05 Oct 2020 18:27:44
	System	05 Oct 2020 18:27:44

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '575eba54-5144-425e-8ec7-e42b1ff3d4ff' User entered '98.9'	System	05 Oct 2020 18:27:44
	System	05 Oct 2020 18:27:44

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '575eba54-5144-425e-8ec7-e42b1ff3d4ff'	System	05 Oct 2020 18:27:44
User entered 'No (N)'	System	05 Oct 2020 18:27:44

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:42', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '575eba54-5144-425e-8ec7-e42b1ff3d4ff' User entered '05 Oct 2020 13:27'	System	05 Oct 2020 18:27:44
	System	05 Oct 2020 18:27:44

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 13:12'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 15:42'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T19:59:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cab373e5-3f7d-443d-ae7c-b5ed4bd2af11' User entered 'Yes (Y)'	System	06 Oct 2020 00:59:50
	System	06 Oct 2020 00:59:50



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T19:59:40', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cab373e5-3f7d-443d-ae7c-b5ed4bd2af11' User entered '98.9'	System	06 Oct 2020 00:59:50
	System	06 Oct 2020 00:59:50

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T19:59:45', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cab373e5-3f7d-443d-ae7c-b5ed4bd2af11' User entered 'No (N)'	System	06 Oct 2020 00:59:50
	System	06 Oct 2020 00:59:50

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T19:59:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cab373e5-3f7d-443d-ae7c-b5ed4bd2af11' User entered '05 Oct 2020 19:59'	System	06 Oct 2020 00:59:50
	System	06 Oct 2020 00:59:50

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 16:37'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 2'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73' User entered 'Yes (Y)'	System	07 Oct 2020 01:44:56
	System	07 Oct 2020 01:44:56

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73' User entered '98.6'	System	07 Oct 2020 01:44:56
	System	07 Oct 2020 01:44:56



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:41', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73'	System	07 Oct 2020 01:44:56
User entered 'Yes (Y)'	System	07 Oct 2020 01:44:56

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
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 'Subject contacted and data updated accordingly' (Site from System).	(b) (4)	09 Oct 2020 14:01:44
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).	Cassandra Zehenny (b) (4)	07 Oct 2020 18:22:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73'	System	07 Oct 2020 01:44:56
User entered '1'	System	07 Oct 2020 01:44:56

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73' User entered '0'	System	07 Oct 2020 01:44:56
	System	07 Oct 2020 01:44:56

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:44:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53fd7ebf-3ad5-433a-8e14-806c3fb2be73' User entered '06 Oct 2020 20:44'	System	07 Oct 2020 01:44:56
	System	07 Oct 2020 01:44:56

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 3'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:09:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '57803f2f-c7da-415e-8666-e33d620e631e' User entered 'Yes (Y)'	System	08 Oct 2020 12:10:13
	System	08 Oct 2020 12:10:13



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '57803f2f-c7da-415e-8666-e33d620e631e' User entered '98.7'	System	08 Oct 2020 12:10:13
	System	08 Oct 2020 12:10:13

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:06', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '57803f2f-c7da-415e-8666-e33d620e631e' User entered 'No (N)'	System	08 Oct 2020 12:10:13
	System	08 Oct 2020 12:10:13

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:10', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '57803f2f-c7da-415e-8666-e33d620e631e' User entered '08 Oct 2020 07:10'	System	08 Oct 2020 12:10:13
	System	08 Oct 2020 12:10:13

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 4'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:14:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5e3ad4f0-6bd4-4c5e-9ad0-d20203cb94da' User entered 'Yes (Y)'	System	09 Oct 2020 10:14:58
	System	09 Oct 2020 10:14:58

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:14:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5e3ad4f0-6bd4-4c5e-9ad0-d20203cb94da' User entered '98.6'	System	09 Oct 2020 10:14:58
	System	09 Oct 2020 10:14:58



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:14:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5e3ad4f0-6bd4-4c5e-9ad0-d20203cb94da' User entered 'No (N)'	System	09 Oct 2020 10:14:58
	System	09 Oct 2020 10:14:58

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:14:55', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5e3ad4f0-6bd4-4c5e-9ad0-d20203cb94da' User entered '09 Oct 2020 05:14'	System	09 Oct 2020 10:14:58
	System	09 Oct 2020 10:14:58

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 5'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:20:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '634b7542-3776-43de-8eee-c42c4747ef65' User entered 'Yes (Y)'	System	10 Oct 2020 02:21:06
	System	10 Oct 2020 02:21:06

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:20:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '634b7542-3776-43de-8eee-c42c4747ef65' User entered '98.9'	System	10 Oct 2020 02:21:06
	System	10 Oct 2020 02:21:06

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:20:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '634b7542-3776-43de-8eee-c42c4747ef65'	System	10 Oct 2020 02:21:06
User entered 'No (N)'	System	10 Oct 2020 02:21:06



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '634b7542-3776-43de-8eee-c42c4747ef65' User entered '09 Oct 2020 21:21'	System	10 Oct 2020 02:21:06
	System	10 Oct 2020 02:21:06

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 6'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:09:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93dc1756-8880-4cbf-a023-895fa1f997ea' User entered 'Yes (Y)'	System	11 Oct 2020 09:09:49
	System	11 Oct 2020 09:09:49

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:09:33', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93dc1756-8880-4cbf-a023-895fa1f997ea' User entered '98.9'	System	11 Oct 2020 09:09:49
	System	11 Oct 2020 09:09:49

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:09:42', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93dc1756-8880-4cbf-a023-895fa1f997ea' User entered 'No (N)'	System	11 Oct 2020 09:09:49
	System	11 Oct 2020 09:09:49

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:09:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93dc1756-8880-4cbf-a023-895fa1f997ea' User entered '11 Oct 2020 04:09'	System	11 Oct 2020 09:09:49
	System	11 Oct 2020 09:09:49



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 7'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0a065b15-b775-4230-9775-af1f0acee7a1' User entered 'Yes (Y)'	System	11 Oct 2020 20:17:24
	System	11 Oct 2020 20:17:24

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:16', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0a065b15-b775-4230-9775-af1f0acee7a1' User entered '98.9'	System	11 Oct 2020 20:17:24
	System	11 Oct 2020 20:17:24

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0a065b15-b775-4230-9775-af1f0acee7a1' User entered 'No (N)'	System	11 Oct 2020 20:17:24
	System	11 Oct 2020 20:17:24

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0a065b15-b775-4230-9775-af1f0acee7a1' User entered '11 Oct 2020 15:17'	System	11 Oct 2020 20:17:24
	System	11 Oct 2020 20:17:24

US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:48', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8b3fba38-fd36-4da3-a4af-645882f157fd' User entered 'None (1)'	System	05 Oct 2020 18:28:02
	System	05 Oct 2020 18:28:02

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8b3fba38-fd36-4da3-a4af-645882f157fd' User entered 'No (N)'	System	05 Oct 2020 18:28:02
	System	05 Oct 2020 18:28:02

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8b3fba38-fd36-4da3-a4af-645882f157fd' User entered 'No (N)'	System	05 Oct 2020 18:28:02
	System	05 Oct 2020 18:28:02

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:27:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8b3fba38-fd36-4da3-a4af-645882f157fd' User entered 'None (1)'	System	05 Oct 2020 18:28:02
	System	05 Oct 2020 18:28:02

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8b3fba38-fd36-4da3-a4af-645882f157fd' User entered '05 Oct 2020 13:28'	System	05 Oct 2020 18:28:02
	System	05 Oct 2020 18:28:02

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 13:12'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 15:42'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T19:59:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '09e54761-e41f-4ba2-af55-a9a0dc81cc6c' User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 01:00:31
	System	06 Oct 2020 01:00:31

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '09e54761-e41f-4ba2-af55-a9a0dc81cc6c' User entered 'No (N)'	System	06 Oct 2020 01:00:31
	System	06 Oct 2020 01:00:31

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:23', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '09e54761-e41f-4ba2-af55-a9a0dc81cc6c' User entered 'No (N)'	System	06 Oct 2020 01:00:31
	System	06 Oct 2020 01:00:31

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '09e54761-e41f-4ba2-af55-a9a0dc81cc6c'	System	06 Oct 2020 01:00:31
User entered 'None (1)'	System	06 Oct 2020 01:00:31

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '09e54761-e41f-4ba2-af55-a9a0dc81cc6c' User entered '05 Oct 2020 20:00'	System	06 Oct 2020 01:00:31
	System	06 Oct 2020 01:00:31

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 16:37'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 2'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:45:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2dcc89f9-2809-48f7-b8c8-a6fc33488b46'	System	07 Oct 2020 01:45:59
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 01:45:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:45:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2dcc89f9-2809-48f7-b8c8-a6fc33488b46'	System	07 Oct 2020 01:45:59
User entered 'No (N)'	System	07 Oct 2020 01:45:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:45:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2dcc89f9-2809-48f7-b8c8-a6fc33488b46'	System	07 Oct 2020 01:45:59
User entered 'No (N)'	System	07 Oct 2020 01:45:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:45:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2dcc89f9-2809-48f7-b8c8-a6fc33488b46'	System	07 Oct 2020 01:45:59
User entered 'None (1)'	System	07 Oct 2020 01:45:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:45:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2dcc89f9-2809-48f7-b8c8-a6fc33488b46' User entered '06 Oct 2020 20:45'	System	07 Oct 2020 01:45:59
	System	07 Oct 2020 01:45:59

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 3'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c6a16485-3160-47a4-8f78-891866ff5949'	System	08 Oct 2020 12:10:38
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 12:10:38

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c6a16485-3160-47a4-8f78-891866ff5949'	System	08 Oct 2020 12:10:38
User entered 'No (N)'	System	08 Oct 2020 12:10:38

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c6a16485-3160-47a4-8f78-891866ff5949'	System	08 Oct 2020 12:10:38
User entered 'No (N)'	System	08 Oct 2020 12:10:38

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:31', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c6a16485-3160-47a4-8f78-891866ff5949'	System	08 Oct 2020 12:10:38
User entered 'None (1)'	System	08 Oct 2020 12:10:38

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'c6a16485-3160-47a4-8f78-891866ff5949' User entered '08 Oct 2020 07:10'	System	08 Oct 2020 12:10:38
	System	08 Oct 2020 12:10:38

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 4'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:05', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cb2e5f61-30da-461f-9cc4-7de12e024bfd'	System	09 Oct 2020 10:15:25
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 10:15:25

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:09', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cb2e5f61-30da-461f-9cc4-7de12e024bfd'	System	09 Oct 2020 10:15:25
User entered 'No (N)'	System	09 Oct 2020 10:15:25

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:13', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cb2e5f61-30da-461f-9cc4-7de12e024bfd'	System	09 Oct 2020 10:15:25
User entered 'No (N)'	System	09 Oct 2020 10:15:25

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:17', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cb2e5f61-30da-461f-9cc4-7de12e024bfd'	System	09 Oct 2020 10:15:25
User entered 'None (1)'	System	09 Oct 2020 10:15:25

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'cb2e5f61-30da-461f-9cc4-7de12e024bfd' User entered '09 Oct 2020 05:15'	System	09 Oct 2020 10:15:25
	System	09 Oct 2020 10:15:25

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 5'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '500e970b-a716-41ed-9612-6c8470f291be' User entered 'None (1)'	System	10 Oct 2020 02:21:26
	System	10 Oct 2020 02:21:26

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:16', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '500e970b-a716-41ed-9612-6c8470f291be' User entered 'No (N)'	System	10 Oct 2020 02:21:26
	System	10 Oct 2020 02:21:26

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '500e970b-a716-41ed-9612-6c8470f291be' User entered 'No (N)'	System	10 Oct 2020 02:21:26
	System	10 Oct 2020 02:21:26

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:21', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '500e970b-a716-41ed-9612-6c8470f291be' User entered 'None (1)'	System	10 Oct 2020 02:21:26
	System	10 Oct 2020 02:21:26

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:24', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '500e970b-a716-41ed-9612-6c8470f291be' User entered '09 Oct 2020 21:21'	System	10 Oct 2020 02:21:26
	System	10 Oct 2020 02:21:26

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 6'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:01', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'bb326d08-c9c8-4933-b5cf-7b5246ec7b95'	System	11 Oct 2020 09:10:15
User entered 'None (1)'	System	11 Oct 2020 09:10:15

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:05', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'bb326d08-c9c8-4933-b5cf-7b5246ec7b95'	System	11 Oct 2020 09:10:15
User entered 'No (N)'	System	11 Oct 2020 09:10:15

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:08', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'bb326d08-c9c8-4933-b5cf-7b5246ec7b95'	System	11 Oct 2020 09:10:15
User entered 'No (N)'	System	11 Oct 2020 09:10:15

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'bb326d08-c9c8-4933-b5cf-7b5246ec7b95'	System	11 Oct 2020 09:10:15
User entered 'None (1)'	System	11 Oct 2020 09:10:15

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'bb326d08-c9c8-4933-b5cf-7b5246ec7b95'	System	11 Oct 2020 09:10:15
User entered '11 Oct 2020 04:10'	System	11 Oct 2020 09:10:15

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 7'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9818a9e3-ffc8-4770-a77d-4bdb5c1ceb25'	System	11 Oct 2020 20:17:36
User entered 'None (1)'	System	11 Oct 2020 20:17:36

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:28', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9818a9e3-ffc8-4770-a77d-4bdb5c1ceb25'	System	11 Oct 2020 20:17:36
User entered 'No (N)'	System	11 Oct 2020 20:17:36

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9818a9e3-ffc8-4770-a77d-4bdb5c1ceb25' User entered 'No (N)'	System	11 Oct 2020 20:17:36
	System	11 Oct 2020 20:17:36

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:33', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9818a9e3-ffc8-4770-a77d-4bdb5c1ceb25'	System	11 Oct 2020 20:17:36
User entered 'None (1)'	System	11 Oct 2020 20:17:36

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:35', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '9818a9e3-ffc8-4770-a77d-4bdb5c1ceb25'	System	11 Oct 2020 20:17:36
User entered '11 Oct 2020 15:17'	System	11 Oct 2020 20:17:36

US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:07', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:10', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:16', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:21', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:28', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'None (0)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered 'No (N)'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T13:28:37', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '93bf981c-24cd-46bc-bec9-dea87b7e8a8a' User entered '05 Oct 2020 13:28'	System	05 Oct 2020 18:28:39
	System	05 Oct 2020 18:28:39

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 13:12'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 15:42'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:00:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:01:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:01:05', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:01:08', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'None (0)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:01:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered 'No (N)'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-05T20:01:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'abc3872d-86bd-4e56-8678-8e7619ca41fc' User entered '05 Oct 2020 20:01'	System	06 Oct 2020 01:01:19
	System	06 Oct 2020 01:01:19

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '05 Oct 2020 16:37'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 2'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:01', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:05', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:10', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:17', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered 'None (0)'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155'	System	07 Oct 2020 01:46:35
User entered 'No (N)'	System	07 Oct 2020 01:46:35

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-06T20:46:33', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '53c56d94-316e-4830-8279-fb6c3a80e155' User entered '06 Oct 2020 20:46'	System	07 Oct 2020 01:46:35
	System	07 Oct 2020 01:46:35



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 3'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:39', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:51', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:55', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:10:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:11:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:11:06', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered 'None (0)'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:11:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2'	System	08 Oct 2020 12:11:18
User entered 'No (N)'	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-08T07:11:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '79d1c815-693e-45ac-a750-760959417fe2' User entered '08 Oct 2020 07:11'	System	08 Oct 2020 12:11:18
	System	08 Oct 2020 12:11:18

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 4'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:45', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01'	System	09 Oct 2020 10:16:23
User entered 'No interference with activity (1)'	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:55', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01'	System	09 Oct 2020 10:16:23
User entered 'No interference with activity (1)'	System	09 Oct 2020 10:16:23



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:15:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered 'None (0)'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:16:07', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered 'None (0)'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:16:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered 'None (0)'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:16:14', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered 'None (0)'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:16:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered 'No (N)'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T05:16:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1ed30c7f-eb53-45df-ae21-304b0bc21b01' User entered '09 Oct 2020 05:16'	System	09 Oct 2020 10:16:23
	System	09 Oct 2020 10:16:23

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 5'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67'	System	10 Oct 2020 02:21:48
User entered 'None (0)'	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67'	System	10 Oct 2020 02:21:48
User entered 'None (0)'	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67'	System	10 Oct 2020 02:21:48
User entered 'None (0)'	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67' User entered 'None (0)'	System	10 Oct 2020 02:21:48
	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:37', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67' User entered 'None (0)'	System	10 Oct 2020 02:21:48
	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:40', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67'	System	10 Oct 2020 02:21:48
User entered 'None (0)'	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:42', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67'	System	10 Oct 2020 02:21:48
User entered 'No (N)'	System	10 Oct 2020 02:21:48



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-09T21:21:45', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3f00ad29-b5d7-4073-b22f-23f0a8a1ce67' User entered '09 Oct 2020 21:21'	System	10 Oct 2020 02:21:48
	System	10 Oct 2020 02:21:48

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 6'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:22', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'None (0)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533'	System	11 Oct 2020 09:11:12
User entered 'No interference with activity (1)'	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:44', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'None (0)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'None (0)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:55', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'None (0)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:10:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'None (0)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:11:03', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered 'No (N)'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T04:11:06', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'aaaf5b5b-d9a9-4036-b0c3-29eb6ccb1533' User entered '11 Oct 2020 04:11'	System	11 Oct 2020 09:11:12
	System	11 Oct 2020 09:11:12

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	05 Oct 2020 17:56:21
User entered 'Day 7'	System	05 Oct 2020 17:56:21

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:39', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:41', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:45', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:47', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'None (0)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered 'No (N)'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-10-11T15:17:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6a3899d2-ee67-4e30-aceea-7a184f8c5421' User entered '11 Oct 2020 15:17'	System	11 Oct 2020 20:17:56
	System	11 Oct 2020 20:17:56

US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 17:56:21



US3552355

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 17:56:21

US3552355

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 14:44:13

US3552355

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:35
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 14:44:13

US3552355

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 14:44:13

US3552355

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 18:19:35
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 14:44:13

US3552355

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:26
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:05:26

US3552355

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	19 Oct 2020 17:05:26

US3552355

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:05:33



US3552355

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:35
User entered '19 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:05:33

US3552355

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:35
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:05:33

US3552355

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	28 Oct 2020 20:12:35
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:12:35
	Stanley Doublin (b) (4)	19 Oct 2020 17:05:33
	(b) (4)	

US3552355

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 13:34:21

US3552355

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	27 Oct 2020 13:34:21

US3552355

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:12:48
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	27 Oct 2020 13:34:42
	(b) (4)	

US3552355

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:48
User entered '27 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 13:34:42

US3552355

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:12:48
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 13:34:42



US3552355

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	28 Oct 2020 20:12:48
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:12:48
	Stanley Doublin (b) (4)	27 Oct 2020 13:34:42
	(b) (4)	

US3552355

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:53:52
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:43

US3552355

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	04 Nov 2020 16:28:43

US3552355

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:53

US3552355

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	16 Nov 2020 00:50:07
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 00:50:07
	Mikayla Frye (b) (4)	10 Nov 2020 20:45:20
	(b) (4)	10 Nov 2020 20:45:20
User entered '04 Nov 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:45:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:08
	(b) (4), (b) (6)	
User entered '4 Nov 2020'	Mikayla Frye (b) (4)	04 Nov 2020 16:28:53
	(b) (4)	

US3552355

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:08
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:53

US3552355

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'VISIT3'	System	04 Nov 2020 16:28:53

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58



US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	04 Nov 2020 16:28:58



US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered empty.	System	04 Nov 2020 16:28:58

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07

US3552355

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07



US3552355

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:22
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:29:11

US3552355

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 16:54:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:54:22
	Mikayla Frye (b) (4)	04 Nov 2020 16:29:11
	(b) (4)	

US3552355

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:30
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:29:21

US3552355

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	23 Nov 2020 01:19:33
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:19:33
	Mikayla Frye (b) (4)	10 Nov 2020 20:45:28
	(b) (4)	10 Nov 2020 20:45:28
User entered '04 Nov 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:45:28
	(b) (4)	10 Nov 2020 20:45:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:30
	(b) (4), (b) (6)	09 Nov 2020 16:54:30
User entered '4 Nov 2020'	Mikayla Frye (b) (4)	04 Nov 2020 16:29:21
	(b) (4)	04 Nov 2020 16:29:21

US3552355

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:30
User entered '10:14'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 16:29:21

US3552355

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered '04 Nov 2020 10:14'	System	10 Nov 2020 20:45:28
User entered '4 Nov 2020 10:14'	System	04 Nov 2020 16:29:21

US3552355

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:28
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Nov 2020 17:50:52

US3552355

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:07
User entered 'I'	System	30 Nov 2020 17:50:52



US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 64'	System	08 Sep 2020 14:41:47

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-11T11:32:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8da26504-6048-4d01-afb8-2d29dfedf2fe'	System	11 Nov 2020 17:32:30
User entered 'No (N)'	System	11 Nov 2020 17:32:30

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-11T11:32:20', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8da26504-6048-4d01-afb8-2d29dfedf2fe'	System	11 Nov 2020 17:32:30
User entered 'No (N)'	System	11 Nov 2020 17:32:30

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-11T11:32:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '8da26504-6048-4d01-afb8-2d29dfedf2fe' User entered '11 Nov 2020 11:32:25'	System	11 Nov 2020 17:32:30
	System	11 Nov 2020 17:32:30

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 14:41:47

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 14:41:47

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered 'Day 71'	System	08 Sep 2020 14:41:47

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-18T19:27:25', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6e1c5541-8c07-4c4e-98b1-bb10ff52633b' User entered 'No (N)'	System	19 Nov 2020 01:27:38
	System	19 Nov 2020 01:27:38



US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-18T19:27:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6e1c5541-8c07-4c4e-98b1-bb10ff52633b'	System	19 Nov 2020 01:27:38
User entered 'No (N)'	System	19 Nov 2020 01:27:38

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-18T19:27:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '6e1c5541-8c07-4c4e-98b1-bb10ff52633b' User entered '18 Nov 2020 19:27:36'	System	19 Nov 2020 01:27:38
	System	19 Nov 2020 01:27:38

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 14:41:47

US3552355

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:23
Data entry locked.	System	08 Sep 2020 14:41:47
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 14:41:47

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-23T13:10:27', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '87e70594-da73-494b-9a46-9df66ad9d5f6' User entered 'No (N)'	System	23 Nov 2020 19:10:37
	System	23 Nov 2020 19:10:37

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-23T13:10:29', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '87e70594-da73-494b-9a46-9df66ad9d5f6' User entered 'No (N)'	System	23 Nov 2020 19:10:37

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-23T13:10:34', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '87e70594-da73-494b-9a46-9df66ad9d5f6' User entered '23 Nov 2020 13:10:34'	System	23 Nov 2020 19:10:37
	System	23 Nov 2020 19:10:37



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-26T07:34:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a055495d-6307-471e-96c2-01b4c91bf0d2'	System	26 Nov 2020 13:35:03
User entered 'No (N)'	System	26 Nov 2020 13:35:03

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-26T07:34:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a055495d-6307-471e-96c2-01b4c91bf0d2'	System	26 Nov 2020 13:35:03
User entered 'No (N)'	System	26 Nov 2020 13:35:03

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-11-26T07:35:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a055495d-6307-471e-96c2-01b4c91bf0d2'	System	26 Nov 2020 13:35:03
User entered '26 Nov 2020 07:35:00'	System	26 Nov 2020 13:35:03

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-04T09:26:42', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '96d944b4-fc97-4ed7-88c6-f194140088b6' User entered 'No (N)'	System	04 Dec 2020 15:26:53
	System	04 Dec 2020 15:26:53

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-04T09:26:45', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '96d944b4-fc97-4ed7-88c6-f194140088b6' User entered 'No (N)'	System	04 Dec 2020 15:26:53
	System	04 Dec 2020 15:26:53

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-04T09:26:49', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '96d944b4-fc97-4ed7-88c6-f194140088b6' User entered '04 Dec 2020 09:26:49'	System	04 Dec 2020 15:26:53
	System	04 Dec 2020 15:26:53

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-12T10:32:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '594327b2-7da6-432f-b886-1f1944ef4266' User entered 'No (N)'	System	12 Dec 2020 16:32:36
	System	12 Dec 2020 16:32:36



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-12T10:32:29', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '594327b2-7da6-432f-b886-1f1944ef4266' User entered 'No (N)'	System	12 Dec 2020 16:32:36
	System	12 Dec 2020 16:32:36

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-12T10:32:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '594327b2-7da6-432f-b886-1f1944ef4266' User entered '12 Dec 2020 10:32:32'	System	12 Dec 2020 16:32:36
	System	12 Dec 2020 16:32:36

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-20T17:59:52', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '295e535a-1f3d-4461-a71f-763375baa971' User entered 'No (N)'	System	21 Dec 2020 00:00:04
	System	21 Dec 2020 00:00:04

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-20T17:59:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '295e535a-1f3d-4461-a71f-763375baa971' User entered 'No (N)'	System	21 Dec 2020 00:00:04
	System	21 Dec 2020 00:00:04

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-20T17:59:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '295e535a-1f3d-4461-a71f-763375baa971' User entered '20 Dec 2020 17:59:59'	System	21 Dec 2020 00:00:04
	System	21 Dec 2020 00:00:04



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-27T06:53:41', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '50b649e4-3d94-4659-81ad-abbdecc043d1' User entered 'No (N)'	System	27 Dec 2020 12:53:50
	System	27 Dec 2020 12:53:50

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-27T06:53:43', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '50b649e4-3d94-4659-81ad-abbdecc043d1' User entered 'No (N)'	System	27 Dec 2020 12:53:50
	System	27 Dec 2020 12:53:50

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2020-12-27T06:53:46', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '50b649e4-3d94-4659-81ad-abbdecc043d1' User entered '27 Dec 2020 06:53:46'	System	27 Dec 2020 12:53:50

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-02T18:53:53', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a89a6683-4f4d-4c92-bec1-4bbd1e620417' User entered 'No (N)'	System	03 Jan 2021 00:54:02
	System	03 Jan 2021 00:54:02

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-02T18:53:56', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a89a6683-4f4d-4c92-bec1-4bbd1e620417'	System	03 Jan 2021 00:54:02
User entered 'No (N)'	System	03 Jan 2021 00:54:02

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-02T18:53:59', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'a89a6683-4f4d-4c92-bec1-4bbd1e620417' User entered '02 Jan 2021 18:53:59'	System	03 Jan 2021 00:54:02

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-08T22:31:26', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0cf26af8-65bd-4004-b080-3c0f190d1a07'	System	09 Jan 2021 04:31:36
User entered 'No (N)'	System	09 Jan 2021 04:31:36



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-08T22:31:29', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0cf26af8-65bd-4004-b080-3c0f190d1a07'	System	09 Jan 2021 04:31:36
User entered 'No (N)'	System	09 Jan 2021 04:31:36

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-08T22:31:32', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '0cf26af8-65bd-4004-b080-3c0f190d1a07' User entered '08 Jan 2021 22:31:32'	System	09 Jan 2021 04:31:36

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-14T18:21:30', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '274c0a5b-e5ac-4a28-9fb1-7da0a5dad1d4' User entered 'No (N)'	System	15 Jan 2021 00:21:38

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-14T18:21:33', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '274c0a5b-e5ac-4a28-9fb1-7da0a5dad1d4'	System	15 Jan 2021 00:21:38
User entered 'No (N)'	System	15 Jan 2021 00:21:38

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-14T18:21:36', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '274c0a5b-e5ac-4a28-9fb1-7da0a5dad1d4' User entered '14 Jan 2021 18:21:36'	System	15 Jan 2021 00:21:38



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-24T17:59:48', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2547045d-f97f-4b7f-b4d1-9cc0c0f2a281' User entered 'No (N)'	System	24 Jan 2021 23:59:57

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-24T17:59:50', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2547045d-f97f-4b7f-b4d1-9cc0c0f2a281' User entered 'No (N)'	System	24 Jan 2021 23:59:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-24T17:59:53', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '2547045d-f97f-4b7f-b4d1-9cc0c0f2a281' User entered '24 Jan 2021 17:59:53'	System	24 Jan 2021 23:59:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 05:59:18



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-31T22:01:12', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3d953b76-fa18-478f-82ec-e8790dc0c5'	System	01 Feb 2021 04:01:23
User entered 'No (N)'	System	01 Feb 2021 04:01:23

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-31T22:01:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3d953b76-fa18-478f-82ec-e8790dc0c5'	System	01 Feb 2021 04:01:23
User entered 'No (N)'	System	01 Feb 2021 04:01:23

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-01-31T22:01:18', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '3d953b76-fa18-478f-82ec-e8790dc0c5'	System	01 Feb 2021 04:01:23
User entered '31 Jan 2021 22:01:18'	System	01 Feb 2021 04:01:23

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-07T18:10:09', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5aadb644-a4f6-428e-b0bb-c2c3ddc3ffd6' User entered 'No (N)'	System	08 Feb 2021 00:10:44
	System	08 Feb 2021 00:10:44



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-07T18:10:11', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5aadb644-a4f6-428e-b0bb-c2c3ddc3ffd6'	System	08 Feb 2021 00:10:44
User entered 'No (N)'	System	08 Feb 2021 00:10:44

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-07T18:10:15', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5aadb644-a4f6-428e-b0bb-c2c3ddc3ffd6' User entered '07 Feb 2021 18:10:15'	System	08 Feb 2021 00:10:44

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-12T20:34:54', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '45721c6b-95ff-4ee0-a15a-d0b3c9112018' User entered 'No (N)'	System	13 Feb 2021 02:35:11
	System	13 Feb 2021 02:35:11

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-12T20:34:57', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '45721c6b-95ff-4ee0-a15a-d0b3c9112018' User entered 'No (N)'	System	13 Feb 2021 02:35:11

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-12T20:35:02', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '45721c6b-95ff-4ee0-a15a-d0b3c9112018' User entered '12 Feb 2021 20:35:02'	System	13 Feb 2021 02:35:11



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-18T16:45:44', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b39faa69-4558-4e34-8c2d-be2bb80c931c' User entered 'No (N)'	System	18 Feb 2021 22:45:58
	System	18 Feb 2021 22:45:58

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-18T16:45:48', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b39faa69-4558-4e34-8c2d-be2bb80c931c' User entered 'No (N)'	System	18 Feb 2021 22:45:58
	System	18 Feb 2021 22:45:58

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-18T16:45:55', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'b39faa69-4558-4e34-8c2d-be2bb80c931c' User entered '18 Feb 2021 16:45:55'	System	18 Feb 2021 22:45:58
	System	18 Feb 2021 22:45:58

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:17:17-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '62da61f3-4ec9-4d18-a458-3b974be54fc6'	System	28 Feb 2021 14:17:33
User entered 'No (N)'	System	28 Feb 2021 14:17:33

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:17:24-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '62da61f3-4ec9-4d18-a458-3b974be54fc6'	System	28 Feb 2021 14:17:33
User entered 'No (N)'	System	28 Feb 2021 14:17:33

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:17:30-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '62da61f3-4ec9-4d18-a458-3b974be54fc6'	System	28 Feb 2021 14:17:33
User entered '28 Feb 2021 07:17:30'	System	28 Feb 2021 14:17:33

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-06T12:00:36-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'caa4360d-20fc-4c4a-9361-57b5c8aa6729'	System	06 Mar 2021 18:00:57
User entered 'No (N)'	System	06 Mar 2021 18:00:57



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-06T12:00:38-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'caa4360d-20fc-4c4a-9361-57b5c8aa6729'	System	06 Mar 2021 18:00:57
User entered 'No (N)'	System	06 Mar 2021 18:00:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-06T12:00:42-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'caa4360d-20fc-4c4a-9361-57b5c8aa6729' User entered '06 Mar 2021 12:00:42'	System	06 Mar 2021 18:00:57
	System	06 Mar 2021 18:00:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-14T18:14:41-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '301125aa-6d1e-4c43-be96-330140414cc1' User entered 'No (N)'	System	14 Mar 2021 23:14:52
	System	14 Mar 2021 23:14:52

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-14T18:14:46-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '301125aa-6d1e-4c43-be96-330140414cc1' User entered 'No (N)'	System	14 Mar 2021 23:14:52

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-14T18:14:50-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '301125aa-6d1e-4c43-be96-330140414cc1' User entered '14 Mar 2021 18:14:50'	System	14 Mar 2021 23:14:52
	System	14 Mar 2021 23:14:52



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-20T12:00:44-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5027c28f-4298-450e-97ae-83e29846efdd'	System	20 Mar 2021 18:00:57
User entered 'No (N)'	System	20 Mar 2021 18:00:57

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-20T12:00:48-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5027c28f-4298-450e-97ae-83e29846efdd'	System	20 Mar 2021 18:00:57
User entered 'No (N)'	System	20 Mar 2021 18:00:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-20T12:00:52-06:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '5027c28f-4298-450e-97ae-83e29846efdd' User entered '20 Mar 2021 12:00:52'	System	20 Mar 2021 18:00:57
	System	20 Mar 2021 18:00:57

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-29T02:57:26-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e7bdbec7-ba14-4f90-8e11-a693a6728245'	System	29 Mar 2021 07:57:44
User entered 'No (N)'	System	29 Mar 2021 07:57:44

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-29T02:57:34-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e7bdbec7-ba14-4f90-8e11-a693a6728245'	System	29 Mar 2021 07:57:44
User entered 'No (N)'	System	29 Mar 2021 07:57:44

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-03-29T02:57:38-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'e7bdbec7-ba14-4f90-8e11-a693a6728245' User entered '29 Mar 2021 02:57:38'	System	29 Mar 2021 07:57:44
	System	29 Mar 2021 07:57:44

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-04T07:00:08-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '173c6a09-5ff3-4ecd-98ed-674ab0fb5090'	System	04 Apr 2021 12:00:29
User entered 'No (N)'	System	04 Apr 2021 12:00:29



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-04T07:00:11-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '173c6a09-5ff3-4ecd-98ed-674ab0fb5090'	System	04 Apr 2021 12:00:29
User entered 'No (N)'	System	04 Apr 2021 12:00:29

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-04T07:00:17-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '173c6a09-5ff3-4ecd-98ed-674ab0fb5090'	System	04 Apr 2021 12:00:29
User entered '04 Apr 2021 07:00:17'	System	04 Apr 2021 12:00:29

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-09T20:28:58-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99ba2bb0-cdb2-4152-90f9-fbe3330acece' User entered 'No (N)'	System	10 Apr 2021 01:29:11

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-09T20:29:03-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99ba2bb0-cdb2-4152-90f9-fbe3330acece' User entered 'No (N)'	System	10 Apr 2021 01:29:11

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-09T20:29:08-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '99ba2bb0-cdb2-4152-90f9-fbe3330acece' User entered '09 Apr 2021 20:29:08'	System	10 Apr 2021 01:29:11
	System	10 Apr 2021 01:29:11



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-16T09:02:39-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1d290f65-155b-4f04-b13d-b953904f7386' User entered 'No (N)'	System	16 Apr 2021 14:02:51
	System	16 Apr 2021 14:02:51

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-16T09:02:41-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1d290f65-155b-4f04-b13d-b953904f7386'	System	16 Apr 2021 14:02:51
User entered 'No (N)'	System	16 Apr 2021 14:02:51

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-16T09:02:46-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '1d290f65-155b-4f04-b13d-b953904f7386' User entered '16 Apr 2021 09:02:46'	System	16 Apr 2021 14:02:51
	System	16 Apr 2021 14:02:51

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-25T18:17:11-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4f693eec-4dbb-4dcf-a3f3-69aueb975939' User entered 'No (N)'	System	25 Apr 2021 23:17:21
	System	25 Apr 2021 23:17:21

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-25T18:17:14-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4f693eec-4dbb-4dcf-a3f3-69aeb975939' User entered 'No (N)'	System	25 Apr 2021 23:17:21

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-25T18:17:17-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '4f693eec-4dbb-4dcf-a3f3-69aaeb975939' User entered '25 Apr 2021 18:17:17'	System	25 Apr 2021 23:17:21
	System	25 Apr 2021 23:17:21

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-30T20:34:03-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '436a55f9-6b8f-4bec-8773-46c336ee86a0'	System	01 May 2021 01:34:12
User entered 'No (N)'	System	01 May 2021 01:34:12



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

Have you been exposed to someone with 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 (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-30T20:34:06-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '436a55f9-6b8f-4bec-8773-46c336ee86a0'	System	01 May 2021 01:34:12
User entered 'No (N)'	System	01 May 2021 01:34:12

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-04-30T20:34:09-05:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: '436a55f9-6b8f-4bec-8773-46c336ee86a0'	System	01 May 2021 01:34:12
User entered '30 Apr 2021 20:34:09'	System	01 May 2021 01:34:12

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:59:18



US3552355

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:59:18

**US3552355**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 05:59:18



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:59:18



US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:59:18



US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:59:18

US3552355

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:59:18

US3552355

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 05:59:18



**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 05:59:18

**US3552355**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:14:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:59:18
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 05:59:18

US3552355

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:14:39**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:17:40-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f865c23f-0b5d-41bc-a4ec-7482e64114fd'	System	06 Mar 2021 18:00:56
User entered 'Yes (Y)'	System	06 Mar 2021 18:00:56

US3552355

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:14:39**

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:18:01-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f865c23f-0b5d-41bc-a4ec-7482e64114fd'	System	06 Mar 2021 18:00:56
User entered 'No (N)'	System	06 Mar 2021 18:00:56

US3552355

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAAAA441-15A3-4FE3-A6C6-37A227FEAAB7)', Time: '2021-02-28T07:18:05-07:00', User OID: 'PatientReportedOutcome (US3552355)', ODM File OID: 'f865c23f-0b5d-41bc-a4ec-7482e64114fd' User entered '28 Feb 2021 07:18:05'	System	06 Mar 2021 18:00:56
	System	06 Mar 2021 18:00:56

US3552355

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:23
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	30 Nov 2020 17:51:03



US3552355

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:23
User entered '30 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	30 Nov 2020 17:51:03

US3552355

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:23
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Nov 2020 17:51:03

US3552355

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:23
User entered empty.	Stanley Doublin (b) (4) (b) (4)	30 Nov 2020 17:51:03

US3552355

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
DataPoint Verified.		18 Mar 2021 17:40:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 20:31:41

US3552355

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:55:06
User entered 'l'	System	04 Jan 2021 20:31:41

US3552355

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:41:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 20:31:52

US3552355

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:41:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '04 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 20:31:52

US3552355

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:41:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 20:31:52



US3552355

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:41:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Jan 2021 20:31:52

US3552355

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:42:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 20:34:33

US3552355

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
User entered 'l'	System	01 Feb 2021 20:34:33

US3552355

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		30 Mar 2021 15:19:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 20:34:44

US3552355

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		30 Mar 2021 15:19:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 20:34:44

US3552355

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		30 Mar 2021 15:19:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 20:34:44

US3552355

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		30 Mar 2021 15:19:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 20:34:44

US3552355

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:43:30



US3552355

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
User entered 'I'	System	11 Feb 2021 22:43:30

US3552355

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:01:52

US3552355

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:01:52

US3552355

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:01:52

US3552355

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:14:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:29
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:01:52

US3552355

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
DataPoint Verified.		18 Mar 2021 17:44:33
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 16:01:57

US3552355

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:49
User entered 'l'	System	01 Mar 2021 16:01:57

US3552355

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:19
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:52:50



US3552355

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:19
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '5 Apr 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:52:50

US3552355

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:19
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Clinic (Clinic)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:52:50

US3552355

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered 'VISIT4'	System	05 Apr 2021 18:52:50

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered empty.	System	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08



US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered empty.	System	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered empty.	System	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered empty.	System	05 Apr 2021 18:53:08



US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:23
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered empty.	System	05 Apr 2021 18:53:08

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32

US3552355

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:14:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32

US3552355

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:26
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:13

US3552355

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:26
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:13

US3552355

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:23

US3552355

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '5 Apr 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:23



US3552355

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:29
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '10:16'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:23

US3552355

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered '5 Apr 2021 10:16'	System	05 Apr 2021 18:53:23

US3552355

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
DataPoint Verified.		09 Apr 2021 16:28:35
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 18:53:27

US3552355

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:32
User entered 'I'	System	05 Apr 2021 18:53:27

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:52:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:35

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:52:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:35

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[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 20:03:45
DataPoint Verified.		18 Mar 2021 17:52:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 15:15:35

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 15:15:35



US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

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 20:03:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:47:38

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
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 18:47:38

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 15:15:46



US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User entered empty.	System	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:14:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User entered empty.	System	21 Jan 2021 15:15:46

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:12

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:12

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '08:16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:12

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:14:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User entered '21 Jan 2021 08:16'	System	21 Jan 2021 15:16:12

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:22



US3552355

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:14:39**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '21 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:22

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
DataPoint Verified.		18 Mar 2021 17:53:21
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User entered '08:20'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Jan 2021 15:16:22

US3552355

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:14:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:45
User entered '21 Jan 2021 08:20'	System	21 Jan 2021 15:16:22

US3552355

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:14:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 03:54:31
User entered 'Yes (Y)'	Heather Douds (b) (4)	18 Sep 2020 17:50:24
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:54:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 15:14:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 15:14:34
Data point term sent to Coder	System	22 Oct 2020 15:12:57
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Resolved per query request. Thank you' (Site from DM).	Cassandra Zehenny (b) (4)	22 Oct 2020 15:12:34
Coding entries removed.	Cassandra Zehenny (b) (4)	22 Oct 2020 15:12:31
User entered 'generalized JOINT ACHES' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	22 Oct 2020 15:12:31
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of JOINT ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:08:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 17:52:38

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Sep 2020 17:52:38
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 17:51:44
User entered 'joint aches'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59



US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 10 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		27 Oct 2020 10:54:55
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 10 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Resolved per query request. Thank you' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	22 Oct 2020 15:12:36
User entered '10 Sep 2020' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	22 Oct 2020 15:12:31
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES IN SEVERAL JOINTS on 10 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:08:14
User entered '15 Sep 2020'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User entered empty.	System	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'No (N)'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '16 Sep 2020'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59



US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User entered empty.	System	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Doubs (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Doubs (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Doubs (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	



US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Related (RELATED)'	Heather Doubs (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	



US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'l'	Heather Doubs (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4)	18 Sep 2020 17:50:59
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User entered '0'	System	18 Sep 2020 17:50:59

US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15
User entered '0'	System	18 Sep 2020 17:50:59



US3552355

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:15

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User closed query 'If swelling is related to preexisting condition, this is not an AE. However, is arthritis worsened while on study, this has to be captured as AE worsening arthritis' (Site from CRA).		28 Oct 2020 20:06:33
Query 'If swelling is related to preexisting condition, this is not an AE. However, is arthritis worsened while on study, this has to be captured as AE worsening arthritis' answered with 'swollen eyes not related to preexisting condition ' (Site from CRA).	Cassandra Zehenny (b) (4)	27 Oct 2020 14:33:54
User opened query 'If swelling is related to preexisting condition, this is not an AE. However, is arthritis worsened while on study, this has to be captured as AE worsening arthritis' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:36:47
Query 'If swelling is related to preexisting condition, this is not an AE. However, is arthritis worsened while on study, this has to be captured as worsening as AE worsening arthritis. ' canceled (Site from CRA).		24 Oct 2020 23:36:26
User opened query 'If swelling is related to preexisting condition, this is not an AE. However, is arthritis worsened while on study, this has to be captured as worsening as AE worsening arthritis. ' (Site from CRA).		24 Oct 2020 23:36:01
User closed query 'Mild swelling captured during PE V2 2+3finger both hands , please consider adding as an AE> ' (Site from CRA).		24 Oct 2020 23:36:01
Query 'Mild swelling captured during PE V2 2+3finger both hands , please consider adding as an AE> ' answered with 'Swelling related to ongoing arthritis and psoriasis captured in Medical History. Need to add as AE if this is normal for him?' (Site from CRA).	Cassandra Zehenny (b) (4)	16 Oct 2020 18:44:36
User opened query 'Mild swelling captured during PE V2 2+3finger both hands , please consider adding as an AE> ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 18:17:46

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Eye swelling, LLT: Swollen eyes - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:08:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:08:54
Data point term sent to Coder	System	07 Oct 2020 19:18:25
User entered 'Swollen eyes'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:00
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:31:00
	Mikayla Frye (b) (4)	10 Nov 2020 20:45:48
	(b) (4)	10 Nov 2020 20:45:48
User entered '06 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:45:48
	(b) (4)	10 Nov 2020 20:45:48
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	07 Oct 2020 19:17:40



US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:11:47
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 19:18:07
User entered '15:00' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	07 Oct 2020 19:18:07
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 19:17:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User entered '06 Oct 2020 15:00'	System	10 Nov 2020 20:45:48
User entered '6 Oct 2020 15:00'	System	07 Oct 2020 19:18:07
User entered empty.	System	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	13 Oct 2020 14:44:50
User entered 'Yes (Y)'	(b) (4)	
	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	11 Nov 2020 18:30:54
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:30:54
	Mikayla Frye (b) (4)	10 Nov 2020 20:45:48
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:45:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '8 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	13 Oct 2020 14:44:50
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User closed query 'Data is required. Please provide.' (Site from System).		16 Oct 2020 04:13:34
Query 'Data is required. Please provide.' answered with 'data not collected' (Site from System).	Stanley Doublin (b) (4)	13 Oct 2020 14:45:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	13 Oct 2020 14:44:50
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User entered empty.	System	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	



US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40



US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	21 Jan 2021 04:15:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 04:15:56
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:54:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:54:45
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:54:45
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Oct 2020 20:11:47
	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	23 Nov 2020 01:20:20
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:31:27
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	16 Nov 2020 16:46:26
DataPoint Un-verified.	(b) (4)	16 Nov 2020 16:46:21
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	16 Nov 2020 16:46:21
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 12:57:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '1'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	23 Nov 2020 01:20:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 01:20:21
	Cassandra Zehenny (b) (4)	16 Nov 2020 16:46:21
User entered '1' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 16:46:21
	Cassandra Zehenny (b) (4)	16 Nov 2020 16:46:21
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40



US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	13 Oct 2020 14:44:50
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:54:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:11:47
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User entered '0'	System	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17
User entered '0'	System	07 Oct 2020 19:17:40

US3552355

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:33:17

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Perioral dermatitis, LLT: Dermatitis perioral - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 21:18:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 21:18:47
Data point term sent to Coder	System	02 Mar 2021 15:07:27
User entered 'Dermatitis around base of nose'	Heather Douds (b) (4)	02 Mar 2021 15:07:05
	(b) (4)	



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '24 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
User entered empty.	System	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:29:56
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Yes (Y)'	(b) (4)	
	Heather Douds (b) (4)	02 Mar 2021 15:07:05
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		09 Apr 2021 16:29:55
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	05 Apr 2021 19:08:39
	(b) (4)	
User entered '10 Mar 2021' reason for change: New Information	Heather Douds (b) (4)	05 Apr 2021 19:08:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
	(b) (4)	
User entered empty.	Heather Douds (b) (4)	02 Mar 2021 15:07:05
	(b) (4)	



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
User entered empty.	System	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		09 Apr 2021 16:30:00
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:08:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	05 Apr 2021 19:08:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4)	02 Mar 2021 15:07:05
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
DataPoint Verified.		18 Mar 2021 17:53:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
User entered '0'	System	02 Mar 2021 15:07:05



US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35
User entered 'I'	System	02 Mar 2021 15:07:05

US3552355

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:37:35

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:50:53
User entered	System	06 Apr 2021 13:50:47
'USA-US089-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 13:50:47

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Lower limb fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 10:30:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 10:30:41
Data point term sent to Coder	System	19 Apr 2021 20:22:10
User closed query 'For coding purposes, please split OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF RIGHT TIBIA into separate entries' (Site from System).	System	19 Apr 2021 20:21:34
Query 'For coding purposes, please split OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF RIGHT TIBIA into separate entries' answered with 'Per PI, these are the same fracture event and will not be separated. Thank you' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	19 Apr 2021 20:21:34
User opened query 'For coding purposes, please split OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF RIGHT TIBIA into separate entries' (Site from System).	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:02:37
User closed query 'PV Query: The event term 'open fracture of right fibula with displaced fracture of right tibia' contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:25:04
Query 'PV Query: The event term 'open fracture of right fibula with displaced fracture of right tibia' contains multiple event terms. Please consider separating them into separate events. ' answered with 'one fracture event, most accurate to keep them combined. ' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 14:06:04
User opened query 'PV Query: The event term 'open fracture of right fibula with displaced fracture of right tibia' contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:15:35
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1871 of 2709

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Apr 2021 19:30:59
User entered 'open fracture of right fibula with displaced fracture of right tibia'	Heather Douds (b) (4)	05 Apr 2021 19:30:53
	(b) (4)	

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53



US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:15:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 11:39:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject has not achieved an end date at this time and it will be provided when achieved, thank you. ' (Site from DM).	Heather Douds (b) (4) (b) (4)	26 Apr 2021 14:28:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:02:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
User entered empty.	Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:03:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:15:27
User entered empty.	System	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Grade 4 (Grade 4)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53



US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
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	05 Apr 2021 19:31:10
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	05 Apr 2021 19:30:53
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
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	05 Apr 2021 19:31:10
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	05 Apr 2021 19:31:10
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:31:10
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	05 Apr 2021 19:30:53
User entered '0'	Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '26 Mar 2021'	(b) (4) Heather Douds (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53



US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Concomitant medication given during hospital stay. Please check the box. ' canceled (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:46:48
DataPoint Verified.		09 Apr 2021 16:45:09
User opened query 'Concomitant medication given during hospital stay. Please check the box. ' (Site from CRA).		09 Apr 2021 16:43:42
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53



US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Could you clarify subject's dose of chlorthalidone; per med records, it is 50 mg/ day ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 12:59:17
Query 'PV Query: Could you clarify subject's dose of chlorthalidone; per med records, it is 50 mg/ day ' answered with 'taking 25 mg 2x daily = 50mg/day; correct as entered' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	13 Apr 2021 19:41:26
User closed query 'PV Query: Could you confirm subject's use of Align, alprazolam, spironolactone, and trazodone as concomitant medications? If so, please add to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:25:11
Query 'PV Query: Could you confirm subject's use of Align, alprazolam, spironolactone, and trazodone as concomitant medications? If so, please add to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:45
User opened query 'PV Query: Could you clarify subject's dose of chlorthalidone; per med records, it is 50 mg/ day ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:15:14
User opened query 'PV Query: Could you confirm subject's use of Align, alprazolam, spironolactone, and trazodone as concomitant medications? If so, please add to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		12 Apr 2021 13:15:07
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT FELL WHILE SKIING AND WAS TRANSPORTED TO ED FOR EVALUATION. On X-ray WAS FOUND TO HAVE OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF TIBIA. INITIALLY placed in orthoglass splint IN ED, THEN UNDERWENT OPEN REDUCTION INTERNAL FIXATION PROCEDURE on 3/25. COVID TESTING NEGATIVE DURING HOSPITAL STAY from 3/25-3/26, was kept overnight for observation. WILL SEND RECORDS TO MEDICAL MONITOR.' reason for change: Data Entry Error	Heather Douds (b) (4)	06 Apr 2021 13:50:58
User entered 'Subject fell while skiing and was transported to ED for evaluation. Was found to have open fracture of right fibula with displaced fracture of tibia. Initially splinted in ED, then underwent open reduction internal fixation procedure. COVID testing negative during hospital stay. Will send records to medical monitor.' reason for change: Data Entry Error	Heather Douds (b) (4)	06 Apr 2021 12:43:40
User entered empty.	Heather Douds (b) (4)	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:30:53

US3552355

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:14:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:30:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:14:39

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:31
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:39:38
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'please see con med #15' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Mar 2021 14:36:13
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:26:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 03:53:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:04

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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.	Coder Import (b) (4)	08 Sep 2020 15:44:49
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Sep 2020 15:44:49
User: Coder System - version WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Sep 2020 15:44:14
User entered 'atorvastatin'	Mikayla Frye (b) (4)	08 Sep 2020 15:43:47
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'hypercholesterolemia'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '20'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	08 Sep 2020 15:43:47
	(b) (4)	



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:43:47
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Jun 2002'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4)	08 Sep 2020 15:43:47
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:43:47



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:43:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:43:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE, PRODUCTSYNONYM: CHLORTHALIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:46
Data point term sent to Coder	System	08 Sep 2020 15:45:15
User entered 'chlorthalidone'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'hypertension'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '25'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:51:36
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:34:07
	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:34:07
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Cassandra Zehenny (b) (4)	12 Apr 2021 16:34:07
Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).		12 Oct 2020 08:11:37
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Resolved' (Site from DM).	Cassandra Zehenny (b) (4)	08 Oct 2020 21:17:18
User entered 'UN Oct 2016' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 21:17:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:07:48
User entered 'un Oct 2006'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:17
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 16:34:07
User entered '1'	System	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 15:44:17

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:44:17

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:46
Data point term sent to Coder	System	08 Sep 2020 15:45:16
User entered 'lisinopril'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'hypertension'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '10'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Oct 2016'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:44:52
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:44:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:44:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:46:47
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 15:46:47
Data point term sent to Coder	System	08 Sep 2020 15:46:17
User entered 'vyvanse'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'attention deficit disorder'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '30'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.		12 Oct 2020 09:05:25
' (Site from DM).		
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.	Cassandra Zehenny (b) (4)	08 Oct 2020 21:18:18
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'UN Nov 2019' reason for change:	Cassandra Zehenny (b) (4)	08 Oct 2020 21:18:11
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.	(b) (4), (b) (6)	08 Oct 2020 14:08:20
' (Site from DM).		
User entered 'un Oct 2016'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:26
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:45:26

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:45:26



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:45:26

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:46:47
Data point term sent to Coder	System	08 Sep 2020 15:46:17
User entered 'venlafaxine'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '150'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Mar 2009'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	08 Sep 2020 15:45:56
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:45:56



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:45:56

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:45:56

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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.	Coder Import (b) (4)	08 Sep 2020 15:47:51
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 15:47:51
Data point term sent to Coder	System	08 Sep 2020 15:47:18
User entered 'vitamin D3'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:21:03
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 16:59:42
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 16:59:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'health'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '1000'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'IU (IU)'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Jun 2002'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:46:33
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 15:46:33

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:46:33

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:47:51
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 15:47:51
Data point term sent to Coder	System	08 Sep 2020 15:47:21
User entered 'fish oil'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:21:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 16:59:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 16:59:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
	(b) (4)	
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'health'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.		13 Oct 2020 10:25:28
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Cassandra Zehenny (b) (4)	08 Oct 2020 21:18:33
' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	08 Oct 2020 14:08:33
' (Site from DM).		
User entered 'I'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '3x/week'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Jan 2018'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Sep 2020 15:47:12

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Mikayla Frye (b) (4)	08 Sep 2020 15:47:12
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:47:12

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:47:12

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:47:12

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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.	Coder Import (b) (4)	30 Oct 2020 04:26:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:56
Data point term sent to Coder	System	29 Oct 2020 15:18:59
Data point term sent to Coder	System	19 Oct 2020 16:30:23
User closed query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	19 Oct 2020 16:29:58
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Zyrtec has one active ingredient- Cetrizine' (Site from System).	Cassandra Zehenny (b) (4)	19 Oct 2020 16:29:58
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	17 Oct 2020 07:47:17
Data point term sent to Coder	System	16 Oct 2020 18:42:14
Coding entries removed.	Cassandra Zehenny (b) (4)	16 Oct 2020 18:41:26

PRODUCTION RELEASE (v12.003  
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2035 of 2709



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	23 Sep 2020 17:03:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:03:34
Data point term sent to Coder	System	23 Sep 2020 15:00:28
User entered 'zyrtec'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
User entered 'SEASONAL ALLERGies' reason for change: Per Query Resolution	Heather Douds (b) (4)	29 Oct 2020 15:18:46
User closed query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies. ' (Site from CRA).	(b) (4)	24 Oct 2020 23:38:39
Query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies. ' answered with 'Updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	16 Oct 2020 18:41:52
User entered 'Seasonal allergy HEADACHE' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	16 Oct 2020 18:41:26
User opened query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 18:14:25
User entered 'headache'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '10'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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).	System	29 Oct 2020 15:18:35
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	29 Oct 2020 15:18:35
User entered 'as needed (PRN)' reason for change:	Heather Douds (b) (4)	29 Oct 2020 15:18:35
Data Entry Error	(b) (4)	
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).	System	29 Oct 2020 15:18:28
User entered 'once (ONCE)'	Stanley Dublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '21 Sep 2020'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User closed query 'Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you! ' (Site from CRA).		04 Nov 2020 18:45:19
Query 'Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you! ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	29 Oct 2020 15:18:52
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	29 Oct 2020 15:18:28
User opened query 'Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:21:29
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:33
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:31:33
	Mikayla Frye (b) (4)	10 Nov 2020 20:46:10
	(b) (4)	10 Nov 2020 20:46:10
User entered '08 Oct 2020' reason for change: New Information	Mikayla Frye (b) (4)	10 Nov 2020 20:46:10
	(b) (4)	09 Nov 2020 16:49:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '8 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	29 Oct 2020 15:18:28
	(b) (4)	23 Sep 2020 14:59:48
User entered empty.	Stanley Dublin (b) (4)	23 Sep 2020 14:59:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User entered empty.	System	23 Sep 2020 14:59:48



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User entered empty.	System	23 Sep 2020 14:59:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:30
User entered empty.	System	23 Sep 2020 14:59:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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)	30 Oct 2020 04:27:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 04:27:27
Data point term sent to Coder	System	29 Oct 2020 15:21:01
Coding entries removed.	Heather Douds (b) (4)	29 Oct 2020 15:20:27
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)	17 Oct 2020 07:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Oct 2020 07:26:39
Data point term sent to Coder	System	16 Oct 2020 18:43:15
Coding entries removed.	Cassandra Zehenny (b) (4)	16 Oct 2020 18:42:42
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)	23 Sep 2020 15:01:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 15:01:41
Data point term sent to Coder	System	23 Sep 2020 15:00:29
User entered 'tylenol'	Stanley Dublin (b) (4)	23 Sep 2020 15:00:23

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2054 of 2709

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:54:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Ongoing in medical history' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 17:02:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:58:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'SEASONAL ALLERGies/HEADACHE' reason for change: Per Query Resolution	Heather Douds (b) (4)	29 Oct 2020 15:20:27
User closed query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:41:42
Query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies' answered with 'Updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	16 Oct 2020 18:42:56
User entered 'Seasonal allergy HEADACHE' reason for change: Per Query Resolution	(b) (4)	16 Oct 2020 18:42:42
User opened query 'Per SC D15, subject cannot differentiate headache from usual season allergies. Please update indication to reflect that headache is related to seasonal allergies' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 18:14:51

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User entered 'headache'	Stanley Dublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '500'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:55:18
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' answered with 'dates are not ongoing' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 17:03:09
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:58:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Dublin (b) (4)	23 Sep 2020 15:00:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
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).	System	29 Oct 2020 15:20:36
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	29 Oct 2020 15:20:36
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).	System	29 Oct 2020 15:20:27
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '21 Sep 2020'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User closed query ' <input type="checkbox"/> Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you' (Site from CRA).		04 Nov 2020 18:47:11
Query ' <input type="checkbox"/> Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	29 Oct 2020 15:20:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 15:20:27
User opened query ' <input type="checkbox"/> Per SC day 15, subject took medicine on 21Sep. Please verify the end date is ongoing. Thank you' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:21:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '21 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	29 Oct 2020 15:20:36
User entered '21 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	29 Oct 2020 15:20:27
User entered empty.	Stanley Dublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User entered empty.	System	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User entered empty.	System	23 Sep 2020 15:00:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:33
User entered empty.	System	23 Sep 2020 15:00:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:17:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:17:12
Data point term sent to Coder	System	05 Oct 2020 19:48:12
User entered 'clobetasol'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:47:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:47:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'psoriatic arthritis'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'l'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Other (OTHER)'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'application'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'other (OTHER)'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'two weeks on then two weeks off'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:47:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Topical (TOPICAL)'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'un Feb 2020'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 19:47:48



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Stanley Doublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 19:47:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Dublin (b) (4)	05 Oct 2020 19:47:48
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:47:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:47:48

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:47:48

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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)	07 Oct 2020 18:25:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:25:00
Data point term sent to Coder	System	07 Oct 2020 18:24:06
User entered 'Tylenol'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE 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 of 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 INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 04:01:21
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE 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 of 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 INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'This occurred within the 7 day post-vaccination diary period, therefore considered an AR, not an AE. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 17:03:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE 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 of 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 INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Nov 2020 06:58:50
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Injection site pain'	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '1000'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:42
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:31:42
	Mikayla Frye (b) (4)	10 Nov 2020 20:46:48
	(b) (4)	10 Nov 2020 20:46:48
User entered '06 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:46:48
	(b) (4)	10 Nov 2020 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31
	(b) (4)	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:43
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 18:31:43
	Mikayla Frye (b) (4)	10 Nov 2020 20:46:48
	(b) (4)	10 Nov 2020 20:46:48
User entered '06 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:46:48
	(b) (4)	10 Nov 2020 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31
	(b) (4)	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User entered empty.	System	07 Oct 2020 18:23:31



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User entered empty.	System	07 Oct 2020 18:23:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:26
User entered empty.	System	07 Oct 2020 18:23:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:04:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:04:18
Data point term sent to Coder	System	13 Oct 2020 14:48:28
User entered 'benadryl'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:55:06
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 17:04:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:39:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'swollen eyes'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '25'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'mg (mg)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:47
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:27
User entered '07 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:47:27
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
User entered '7 Oct 2020'	Stanley Dublin (b) (4)	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	11 Nov 2020 18:31:48
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:27
User entered '07 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 20:47:27
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
User entered '7 Oct 2020'	Stanley Dublin (b) (4)	13 Oct 2020 14:47:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:06:57
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		02 Dec 2020 04:55:18
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	30 Nov 2020 17:03:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 17:03:50
User entered 'No (N)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Nov 2020 17:03:50
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:40:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User entered empty.	System	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User entered empty.	System	13 Oct 2020 14:47:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:46
User entered empty.	System	13 Oct 2020 14:47:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
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)	30 Nov 2020 17:53:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 17:53:19
Data point term sent to Coder	System	30 Nov 2020 17:52:42
Coding entries removed.	Stanley Doublin (b) (4)	30 Nov 2020 17:51:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
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)	27 Oct 2020 14:05:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:05:00
Data point term sent to Coder	System	27 Oct 2020 13:43:09
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:07:03
DataPoint Un-verified.	Stanley Doublin (b) (4)	30 Nov 2020 17:51:50
User entered 'influenza Prophylaxis' reason for change: Data Entry Error	Stanley Doublin (b) (4)	30 Nov 2020 17:51:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'prophylaxis'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:14:00
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	Cassandra Zehenny (b) (4)	28 Jan 2021 20:21:12
User entered 'l'	(b) (4), (b) (6)	28 Jan 2021 03:28:46
	(b) (4), (b) (6)	09 Nov 2020 16:49:02
	Stanley Dublin (b) (4)	27 Oct 2020 13:42:40



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4)	09 Nov 2020 16:49:02
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	31 Jan 2021 04:01:59
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Jan 2021 20:21:07
User entered 'injection' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Jan 2021 20:21:07
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'cc'	Stanley Dublin (b) (4)	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered empty.	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '26 Oct 2020'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '0'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered '26 Oct 2020'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:55:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:02
User entered 'No (N)'	Stanley Doublin (b) (4)	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User entered empty.	System	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User entered empty.	System	27 Oct 2020 13:42:40

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:49
User entered empty.	System	27 Oct 2020 13:42:40

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 08:35:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 08:35:56
Data point term sent to Coder	System	02 Mar 2021 15:07:27
Data point term sent to Coder	System	02 Mar 2021 15:06:26
Coding entries removed.	Heather Douds (b) (4)	02 Mar 2021 15:06:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Mar 2021 10:43:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:43:12
Data point term sent to Coder	System	01 Mar 2021 16:04:47
User entered 'doxycycline'	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	(b) (4) Mikayla Frye (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'DERMATITIS around base of nose'	(b) (4)	
reason for change: Data Entry Error	Heather Douds (b) (4)	02 Mar 2021 15:07:20
User entered 'DERMATITIS' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	02 Mar 2021 15:06:02
User entered 'dermatitist'	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data	(b) (4)	
required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not	(b) (4)	
required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '100'	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'twice daily (BID)'	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '24 Feb 2021'	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered '0'	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'Yes (Y)'	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
User entered '10 Mar 2021' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 18:54:27
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered empty.	(b) (4)	
	Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
	(b) (4)	
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
DataPoint Verified.		18 Mar 2021 17:50:51
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	(b) (4) Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 20:47:10

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
User entered '2'	System	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
User entered '1'	System	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:20:41
User entered '804 (804)'	System	01 Mar 2021 16:04:43
DataPoint activated with code reason code Data required.	Stanley Doublin (b) (4)	01 Mar 2021 16:02:48
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	10 Nov 2020 20:47:10



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 23:39:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 23:39:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:37:57
Data point term sent to Coder System		23 Mar 2021 14:37:29
User entered 'dermal filler'	Cassandra Zehenny (b) (4) (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'post left periorbital fracture'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'Other (OTHER)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'injection'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'other (OTHER)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'twice a year'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'un UNK 2016'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:18:40
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:37:57
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	23 Mar 2021 14:37:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:37:11



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:37:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:37:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:45:24
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 19:45:24
Data point term sent to Coder	System	05 Apr 2021 19:44:31
User entered 'eliquis'	Stanley Dublin (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '5'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'twice daily (BID)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 15:13:47
DataPoint Un-verified.	Heather Douds (b) (4)	26 Apr 2021 14:16:07
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	26 Apr 2021 14:16:07
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	26 Apr 2021 14:16:07
User closed query 'Per source - end date 17Apr2021. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:58:36
Query 'Per source - end date 17Apr2021. Please reconcile. ' answered with 'unable to enter future dates in EDC; will update when we reach 17APR2021' (Site from CRA).	Heather Douds (b) (4)	09 Apr 2021 18:08:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User opened query 'Per source - end date 17Apr2021. Please reconcile. ' (Site from CRA).		09 Apr 2021 16:53:20
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	05 Apr 2021 19:43:42
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 15:13:47
DataPoint Un-verified.	Heather Douds (b) (4)	26 Apr 2021 14:16:07
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	26 Apr 2021 14:16:07
	(b) (4)	
User entered '17 Apr 2021' reason for change: New Information	Heather Douds (b) (4)	26 Apr 2021 14:16:07
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered empty.	Stanley Dublin (b) (4)	05 Apr 2021 19:43:42
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:43:42

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 19:43:42

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:43:42

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:43:42

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFLEXIN, PRODUCTSYNONYM: KEFLEX [CEFLEXIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 12:27:54
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 Apr 2021 12:27:54
Data point term sent to Coder	System	05 Apr 2021 19:45:32
User entered 'keflex'	Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '500'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once daily (QD)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	15 Apr 2021 19:22:57
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 18:59:49
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:09:39
Signature has been broken.	(b) (4)	09 Apr 2021 18:09:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:09:39
DataPoint Verified.	(b) (4)	09 Apr 2021 17:04:45
User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 15:13:17
User entered 'No (N)'	sharon frey (b) (4)	05 Apr 2021 19:44:58
	(b) (4)	
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 19:00:05
User closed query 'Please update source end dates , per medical records. ' (Site from CRA).		09 Apr 2021 18:59:35
Query 'Please update source end dates , per medical records. ' answered with 'updated to reflect ongoing' (Site from CRA).	Heather Douds (b) (4)	09 Apr 2021 18:09:47
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	09 Apr 2021 18:09:39
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:09:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:09:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User opened query 'Please update source end dates , per medical records. ' (Site from CRA).		09 Apr 2021 16:54:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	05 Apr 2021 19:45:19
User entered '25 Mar 2021' reason for change: Data Entry Error	Stanley Dublin (b) (4)	05 Apr 2021 19:45:19
	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	05 Apr 2021 19:44:58
User entered empty.	Stanley Dublin (b) (4)	05 Apr 2021 19:44:58
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:57
DataPoint Un-verified.		15 Apr 2021 19:22:52
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:44:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Apr 2021 19:44:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:44:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:44:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 04:11:41
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 Apr 2021 04:11:41
Data point term sent to Coder	System	05 Apr 2021 19:46:36
User entered 'oxycodone'	Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:45:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '5'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:05
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered 'No (N)'	Stanley Dublin (b) (4)	05 Apr 2021 19:45:53
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:07
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered '25 Mar 2021'	Stanley Dublin (b) (4)	05 Apr 2021 19:45:53
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:45:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:45:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:45:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:45:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:11:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:11:13
Data point term sent to Coder	System	05 Apr 2021 19:46:34
User entered 'senna'	Stanley Dublin (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'tablet (TABLET)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:46:31



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:29
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:13
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:13
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered 'No (N)'	Stanley Dublin (b) (4)	05 Apr 2021 19:46:31
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:29
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:13
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:13
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered '25 Mar 2021'	Stanley Dublin (b) (4)	05 Apr 2021 19:46:31
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:46:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:46:31



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:46:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:46:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
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)	05 Apr 2021 19:48:24
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 19:48:24
Data point term sent to Coder	System	05 Apr 2021 19:47:37
User entered 'tylenol'	Stanley Doublin (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '1000'	(b) (4) Stanley Doublin (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:30
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	05 Apr 2021 19:47:28
	(b) (4)	
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	05 Apr 2021 19:47:21
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:18:30
DataPoint Un-verified.	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4)	09 Apr 2021 18:10:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Apr 2021 19:47:28
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Apr 2021 19:47:21
User entered '25 Mar 2021'	Stanley Dublin (b) (4)	05 Apr 2021 19:47:21
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Apr 2021 19:47:21

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:47:21

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:47:21

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:47:21

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:08:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:08:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:28:10
User entered 'Cefazolin'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '2000'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:27:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
User entered empty.	System	06 Apr 2021 14:27:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
User entered empty.	System	06 Apr 2021 14:27:53

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:31
User entered empty.	System	06 Apr 2021 14:27:53

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:29:11
User entered 'dexamethasone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '10'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:28:45

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
User entered empty.	System	06 Apr 2021 14:28:45

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
User entered empty.	System	06 Apr 2021 14:28:45

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:20
User entered empty.	System	06 Apr 2021 14:28:45



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:36
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:30:12
User entered 'dexmedetomidine'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '20'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'ug (ug)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:29:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
User entered empty.	System	06 Apr 2021 14:29:47



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
User entered empty.	System	06 Apr 2021 14:29:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:24
User entered empty.	System	06 Apr 2021 14:29:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:31:12
User entered 'fentanyl'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '75'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'ug (ug)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:30:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
User entered empty.	System	06 Apr 2021 14:30:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
User entered empty.	System	06 Apr 2021 14:30:52

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:28
User entered empty.	System	06 Apr 2021 14:30:52

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:32:13
User entered 'fentanyl'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '200'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'ug (ug)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:31:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
User entered empty.	System	06 Apr 2021 14:31:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
User entered empty.	System	06 Apr 2021 14:31:31

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:49
User entered empty.	System	06 Apr 2021 14:31:31

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:32:13
User entered 'hydromorphone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
User entered empty.	System	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
User entered empty.	System	06 Apr 2021 14:32:11

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:51
User entered empty.	System	06 Apr 2021 14:32:11



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:33:14
User entered 'hydromorphone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0.4'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:32:43

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
User entered empty.	System	06 Apr 2021 14:32:43



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
User entered empty.	System	06 Apr 2021 14:32:43

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:36
User entered empty.	System	06 Apr 2021 14:32:43

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:06:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:33:14
User entered 'hydromorphone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0.5'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:33:09

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
User entered empty.	System	06 Apr 2021 14:33:09

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
User entered empty.	System	06 Apr 2021 14:33:09

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:39
User entered empty.	System	06 Apr 2021 14:33:09

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:34:18
User entered 'lidocaine'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '100'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
User entered empty.	System	06 Apr 2021 14:34:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
User entered empty.	System	06 Apr 2021 14:34:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:32
User entered empty.	System	06 Apr 2021 14:34:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:13:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 07:48:47
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 07:48:47
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	(b) (4) System	06 Apr 2021 14:35:19
User entered 'magnesium sulfate'	Heather Douds (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '2'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'g (g)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:34:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
User entered empty.	System	06 Apr 2021 14:34:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
User entered empty.	System	06 Apr 2021 14:34:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:58
User entered empty.	System	06 Apr 2021 14:34:47



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:24:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:36:21
User entered 'midazolam'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '2'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
User entered empty.	System	06 Apr 2021 14:35:23



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
User entered empty.	System	06 Apr 2021 14:35:23

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:01
User entered empty.	System	06 Apr 2021 14:35:23

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:36:20
User entered 'morphine'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '2'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:35:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
User entered empty.	System	06 Apr 2021 14:35:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
User entered empty.	System	06 Apr 2021 14:35:58

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:04
User entered empty.	System	06 Apr 2021 14:35:58

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:37:21
User entered 'morphine'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	06 Apr 2021 14:36:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 14:36:31
User entered 'open reduction internal fixation' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:31
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 14:36:25
User entered empty.	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '4'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:36:25

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
User entered empty.	System	06 Apr 2021 14:36:25

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
User entered empty.	System	06 Apr 2021 14:36:25

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:13
User entered empty.	System	06 Apr 2021 14:36:25

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:35:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:35:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:37:22
User entered 'zofran'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '4'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:01

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
User entered empty.	System	06 Apr 2021 14:37:01

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
User entered empty.	System	06 Apr 2021 14:37:01

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:15
User entered empty.	System	06 Apr 2021 14:37:01



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:47:42
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:38:23
User entered 'propofol'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '140'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:37:32

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
User entered empty.	System	06 Apr 2021 14:37:32



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
User entered empty.	System	06 Apr 2021 14:37:32

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:22:18
User entered empty.	System	06 Apr 2021 14:37:32

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.	(b) (4)	09 Apr 2021 17:04:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:05:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:05:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
Data point term sent to Coder	System	06 Apr 2021 14:38:24
User entered 'rocuronium'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '40'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
User entered empty.	System	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
User entered empty.	System	06 Apr 2021 14:38:15

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:00
User entered empty.	System	06 Apr 2021 14:38:15

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 14:41:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 14:41:05
Data point term sent to Coder	System	06 Apr 2021 14:39:26
User entered 'lactated ringers'	Heather Douds (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '1000'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mL (mL)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once (ONCE)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 08:14:39**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
DataPoint Verified.		09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
User entered empty.	System	06 Apr 2021 14:39:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
User entered empty.	System	06 Apr 2021 14:39:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:21:04
User entered empty.	System	06 Apr 2021 14:39:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 14:41:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:41:05
Data point term sent to Coder	System	06 Apr 2021 14:40:30
User entered 'trazadone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'anxiety'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '50'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'as needed (PRN)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:47

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:47



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please verify if Ambien 5mg PRN, Hydralazine 10mg IV PRN, Hydromorphone 0.2mg IV PRN, Miralax 17g PRN, Phenergan 12 g PRN should be added to conmeds. Please refer to PCP notes , page 10 Consultation notes. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 19:01:38
Query 'Please verify if Ambien 5mg PRN, Hydralazine 10mg IV PRN, Hydromorphone 0.2mg IV PRN, Miralax 17g PRN, Phenergan 12 g PRN should be added to conmeds. Please refer to PCP notes , page 10 Consultation notes. Thank you! ' answered with 'meds were entered from hospitalization based on "administered medications" not general medication list, as the administered meds were actually given, not just ordered. data correct as entered.' (Site from CRA).	Heather Douds (b) (4) (b) (4)	09 Apr 2021 18:12:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User opened query 'Please verify if Ambien 5mg PRN, Hydralazine 10mg IV PRN, Hydromorphone 0.2mg IV PRN, Miralax 17g PRN, Phenergan 12 g PRN should be added to conmeds. Please refer to PCP notes , page 10 Consultation notes. Thank you! ' (Site from CRA).		09 Apr 2021 17:02:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	06 Apr 2021 15:13:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:41:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:41:36
Data point term sent to Coder	System	06 Apr 2021 14:40:29
User entered 'spironolactone'	Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'hypertension'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '50'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'once daily (QD)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	06 Apr 2021 14:40:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:04:45
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	06 Apr 2021 14:40:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	06 Apr 2021 14:40:18



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 14:40:18

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 14:40:18

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: BIFIDOBACTERIUM INFANTIS, PRODUCTSYNONYM: ALIGN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Apr 2021 13:46:08
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 Apr 2021 13:46:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:35:09
Data point term sent to Coder	System	12 Apr 2021 16:38:06
User entered 'align [bifidobacterium longum]'	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:13

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:13

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'health promotion'	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:13

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered '4'	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:13

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered empty.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	



US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered empty.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 16:37:13

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered empty.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered '01 Feb 2021'	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered '0'	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:09
User entered empty.	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	



US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	12 Apr 2021 20:35:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 20:35:09
	Cassandra Zehenny (b) (4)	12 Apr 2021 16:37:13
	(b) (4)	

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:37:13

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:37:13

US3552355

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 08:14:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 16:37:13

US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:14:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:31
DataPoint Verified.	(b) (4)	09 Apr 2021 16:32:37
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:31:41
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:31:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	05 Apr 2021 19:31:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:40:33
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:00:26
	(b) (4)	
User entered 'No (N)'	Stanley Doublin (b) (4)	01 Mar 2021 16:02:03
	(b) (4)	

US3552355

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:14:39**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '25 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:33:30

US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:14:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'open reduction internal fixation'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:33:30

US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:14:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:33:30



US3552355

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:14:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:32:57
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	05 Apr 2021 19:33:30

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'USA-US089-2021-MRNA-1273-P301000007'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'sharon'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'frey'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'MO'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'US'	(b) (4) System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 17:39:23
User entered '3'	System	13 Apr 2021 17:24:07
User entered '2'	System	06 Apr 2021 15:26:00
User entered '1'	System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'USA-US089-2021-MRNA-1273-P301000007'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'sharon'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'frey'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'MO'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'US'	(b) (4) System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 17:39:23
User entered '3'	System	13 Apr 2021 17:24:07
User entered '2'	System	06 Apr 2021 15:26:00
User entered '1'	System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:14:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered '06/Apr/2021 13:54'	(b) (4) System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:14:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'USA-US089-2021-MRNA-1273-P301000007'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'sharon'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'frey'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'MO'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'US'	(b) (4) System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 17:39:23
User entered '3'	System	13 Apr 2021 17:24:07
User entered '2'	System	06 Apr 2021 15:26:00
User entered '1'	System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:14:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered '06/Apr/2021 15:25'	(b) (4) System	06 Apr 2021 15:26:00

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:14:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
Reviewed for Safety.		13 Apr 2021 17:22:39
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	08 Apr 2021 14:28:17
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:26:00

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered	System	06 Apr 2021 13:50:47
'USA-US089-2021-MRNA-1273-P301000007'		

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'sharon'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'frey'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'MO'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'US'	(b) (4) System	06 Apr 2021 13:54:04



**US3552355**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:14:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 17:39:23
User entered '3'	System	13 Apr 2021 17:24:07
User entered '2'	System	06 Apr 2021 15:26:00
User entered '1'	System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:14:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	16 Apr 2021 15:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:09
DataPoint Verified.		14 Apr 2021 15:50:03
User entered '13/Apr/2021 13:24'	System	13 Apr 2021 17:24:07

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:14:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	16 Apr 2021 15:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:09
Reviewed for Safety.		14 Apr 2021 17:46:13
DataPoint Verified.		14 Apr 2021 15:50:03
User entered 'l'		13 Apr 2021 17:24:07

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'USA-US089-2021-MRNA-1273-P301000007'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'Yes (Y)'	System	06 Apr 2021 13:50:47



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'No (N)'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'sharon'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'frey'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:53:57
User entered 'MO'	System	06 Apr 2021 13:50:47

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:12
DataPoint Un-verified.		16 Apr 2021 15:57:09
DataPoint Verified.		09 Apr 2021 16:45:17
Reviewed for Safety.		06 Apr 2021 15:25:44
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:17
User entered 'US'	(b) (4) System	06 Apr 2021 13:54:04

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Apr 2021 17:39:23
User entered '3'	System	13 Apr 2021 17:24:07
User entered '2'	System	06 Apr 2021 15:26:00
User entered '1'	System	06 Apr 2021 13:54:04



US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:14:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	16 Apr 2021 15:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:09
DataPoint Verified.		15 Apr 2021 19:22:25
User entered '14/Apr/2021 13:39'	System	14 Apr 2021 17:39:23

US3552355

Folder: SAE USA-US089-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:14:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:19
DataPoint Verified.	(b) (4)	16 Apr 2021 15:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:57:09
DataPoint Verified.		15 Apr 2021 19:22:25
Reviewed for Safety.		14 Apr 2021 17:46:13
User entered 'l'		14 Apr 2021 17:39:23