

US3662181 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:20:38

All time stamps listed in this document are displayed in GMT

**US3662181**

**Form: Participant Creation**

**Data signed:** (b) (4) 18 Mar 2021 22:22:55

**Generated On: 10 Jun 2021 09:20:38**

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[Participant ID](#)

US3662181

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

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**US3662181**

**Folder: Screening**

**Form: Visit Date**

**Data signed:** (b) (4) 18 Mar 2021 22:22:56

**Generated On: 10 Jun 2021 09:20:38**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	SCRN

US3662181

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" 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	True
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

US3662181

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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

US3662181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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**US3662181**

**Folder: Screening**

**Form: Medical History Summary**

**Data signed:** (b) (4) 18 Mar 2021 22:22:56

**Generated On: 10 Jun 2021 09:20:38**

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Were any significant conditions reported?

Yes ☒

No ☐

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US3662181

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	HYPERLIPIDEMIA, UNSPECIFIED
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3662181

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	LOW VON WILLEBRAND FACTOR
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	15 JUL 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	UNSPECIFIED GLAUCOMA
Start date (dd MMM yyyy)	15 JUL 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	HYPERPARATHYROIDISM
Start date (dd MMM yyyy)	15 JUL 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	BIPOLAR AFFECTIVE DISORDER UNSPECIFIED
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	GENERALIZED ANXIETY DISORDER
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	MAJOR DEPRESSIVE DISORDER RECUR EPIS MILD
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	SCHIZO-AFFECT SHIZO UNSPECIFIED CONDITION
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	



US3662181

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	UNSPECIFIED ANEMIA
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	CHRONIC KIDNEY DISEASE STG. IV
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	UNSPECIFIED RETENTION OF URINE
Start date (dd MMM yyyy)	22 JUN 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	BENIGN NEOPLASM OF BRAIN
Start date (dd MMM yyyy)	15 JUL 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	OTHER CONVULSIONS
Start date (dd MMM yyyy)	15 JUL 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662181

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Condition	SUICIDAL IDEATION
Start date (dd MMM yyyy)	10 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)	

US3662181

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:35
Height (xxx.x)	171.5 cm
Weight (xxx.x)	96.9 kg
BMI (xxx.x)	32.94546 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)	

US3662181

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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



US3662181

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

US3662181

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

<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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	VISIT1

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

What was the date of randomization? (dd MMM yyyy) 22 OCT 2020

What was the participant's randomization number? 117833

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 ☒

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 18 Mar 2021 22:22:57

**Generated On: 10 Jun 2021 09:20:38**

Height	ND - Not Done
Weight	ND - Not Done

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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)	22 OCT 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:35
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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)	22 OCT 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:59
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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.*



US3662181

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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) 22 OCT 2020

What was the treatment time? (00:00-23:59) 13:14 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 13:14

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

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

22 OCT 2020 11:55

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	22 OCT 2020 11:50
Nasopharyngeal Swab 2	No		

US3662181

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 13:53

PC Open Date & Time

22 OCT 2020 13:34

PC Close Date & Time

22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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 97.6 °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	22 OCT 2020 23:06
PC Open Date & Time	22 OCT 2020 16:59
PC Close Date & Time	23 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 20:10

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 19:35

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 20:28

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 13:41

PC Open Date & Time

22 OCT 2020 13:34

PC Close Date & Time

22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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

22 OCT 2020 23:07

PC Open Date & Time

22 OCT 2020 16:59

PC Close Date & Time

23 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

**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

23 OCT 2020 20:10

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

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

3

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

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

Yes ☐

No ☒

Please record - **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

24 OCT 2020 19:37

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**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

25 OCT 2020 20:29

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 13:42
PC Open Date & Time	22 OCT 2020 13:34
PC Close Date & Time	22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 23:07
PC Open Date & Time	22 OCT 2020 16:59
PC Close Date & Time	23 OCT 2020 11:59



US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

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

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 19:37
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 20:30
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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 ☐

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes ☐

PC Time stamp

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59



US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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)

64 of 2247

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**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)

66 of 2247

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments  
*If Contact Not Made, please provide Comments*

CALLED AND TEXTED  
PARTICIPANT- LEFT MESSAGE.  
PHONE WENT STRAIGHT TO  
VOICE MAIL

US3662181

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

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

**Form: Safety Call**

**Data signed:** (b) (4) 18 Mar 2021 22:22:56

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT2

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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)	19 NOV 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 09:52
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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)	19 NOV 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

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) 19 NOV 2020

What was the treatment time? (00:00-23:59) 10:39 (24 HR)

Treatment Date and Time (derived) 19 NOV 2020 10:39

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

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

19 NOV 2020 10:15



US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Collection date (dd MMM yyyy)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:10	19 NOV 2020 10:10
Nasopharyngeal Swab 2	No		

US3662181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**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

19 NOV 2020 11:09

PC Open Date & Time

19 NOV 2020 10:59

PC Close Date & Time

19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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 98.3 °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	19 NOV 2020 22:26
PC Open Date & Time	19 NOV 2020 14:24
PC Close Date & Time	20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 19:15

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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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

97.3 °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

21 NOV 2020 19:18

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 NOV 2020 20:09

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 20:42

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59



US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 NOV 2020 09:26

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 NOV 2020 01:50

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**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

19 NOV 2020 11:10

PC Open Date & Time

19 NOV 2020 10:59

PC Close Date & Time

19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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

19 NOV 2020 22:26

PC Open Date & Time

19 NOV 2020 14:24

PC Close Date & Time

20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

**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

20 NOV 2020 19:16

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

**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

21 NOV 2020 19:19

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**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

22 NOV 2020 20:10

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

**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

23 NOV 2020 20:43

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59



US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

**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

25 NOV 2020 09:26

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**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

26 NOV 2020 01:51

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 11:10
PC Open Date & Time	19 NOV 2020 10:59
PC Close Date & Time	19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 22:27
PC Open Date & Time	19 NOV 2020 14:24
PC Close Date & Time	20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:20:38

**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

102 of 2247

EAB) (1725)

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 19:17
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59



US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 19:19
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:20:38

**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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 20:10
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 20:43
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

110 of 2247

EAB) (1725)

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 09:27
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59



US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**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 ☒

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

Yes <input type="checkbox"/>	
PC Time stamp	26 NOV 2020 01:51
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 18 Mar 2021 22:22:56

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

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

**Form: Safety Call**

**Data signed:** (b) (4) 18 Mar 2021 22:22:56

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3662181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 DEC 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

US3662181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	10:14 (24 HR)
Vital Signs Date and Time (derived)	17 DEC 2020 10:14
Temperature ( <i>xxx.x</i> )	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 DEC 2020

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

US3662181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 DEC 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

17 DEC 2020 10:20

US3662181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:57

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 00:25:30

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 68
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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2020 23:59
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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 20:39:57
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

20 JAN 2021 12:05:09

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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	27 JAN 2021 11:32:12
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

03 FEB 2021 14:41:24

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

13 FEB 2021 20:13:38

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

20 FEB 2021 14:29:47

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 20:22:53

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

06 MAR 2021 00:03:05

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

13 MAR 2021 18:55:59

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

20 MAR 2021 12:57:32

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 12:28:25
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

12 APR 2021 16:31:24

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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

25 APR 2021 10:41:54

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 17:13:40
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59



US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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°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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59



US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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°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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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°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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59



US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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 <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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

12 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2022 23:59
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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

**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 ☐

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

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[Patient Cloud Open Date & Time](#)

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17 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2022 23:59

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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:38

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"/>

**US3662181**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

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

**US3662181**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:20:38**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 20:23:26

US3662181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 08 Apr 2021 21:59:04

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3662181

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 28 Apr 2021 13:43:14

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3662181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:38

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3662181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:38

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.*

**US3662181**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3662181**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3662181**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:20:38**

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"/>

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3662181

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

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

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

Visit date (dd MMM yyyy)	12 FEB 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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US3662181

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Date of updated informed consent ( <i>dd MMM yyyy</i> )	12 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	12 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3662181**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 18 Mar 2021 22:22:55

**Generated On: 10 Jun 2021 09:20:38**

Height	171.45 cm
Weight	99.51 kg
BMI (xxx.x)	33.85258

US3662181

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Height	171.45 cm
Weight	99.51 kg
BMI (xxx.x)	33.85258
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 09:32
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Height	171.45 cm
Weight	99.51 kg
BMI (xxx.x)	33.85258
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 10:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

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

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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



US3662181

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

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 10:05

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

US3662181

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	12 FEB 2021 09:45

US3662181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00 - 23:59)	09:42
Collection Date and Time (derived)	12 FEB 2021 09:42

US3662181

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

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3662181

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3662181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 09:57
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



US3662181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 11:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

12 MAR 2021

---

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

---

US3662181

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 MAR 2021

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 10:35

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

US3662181

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 08 Apr 2021 21:59:04

**Generated On: 10 Jun 2021 09:20:38**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3662181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	OLD57

US3662181

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 APR 2021
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 10:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3662181

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

9 APR 2021

---

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

---

US3662181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 APR 2021
Collection time (00:00-23:59)	10:39 (24 HR)
Collection date and time (derived)	9 APR 2021 10:39

US3662181

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

AEID	USA-US088-2020-MRNA-1273-P30 1000003
Adverse event	SCHIZOAFFECTIVE DISORDERS, WORSENING
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)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	363 of 2247

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

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

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

---

HISTORY OF PRESENT ILLNESS:

61 YEAR OLD MALE WITH A  
HISTORY OF BAD,  
SCHIZOPHRENIA WHO  
PRESENTED TO PES LOBBY  
WITH CASE MANGER  
YESTERDAY AFTER BEING AT  
STORE AND TALKING TO THE  
CASE MANAGER ABOUT  
OBTAINING A FIREARM TO  
SHOOT PEOPLE

PSYCHIATRIC HISTORY: HX  
BAD, SCHIZOPHRENIA,  
PARANOIA. PT LONG TIME  
OUTPT FOLLOW UP WITH  
CENTRAL CLINIC CM. PT HAS  
APPROX 4 SUICIDE ATTEMPTS  
IN HIS HISTORY, INCLUDING

(b) (6).  
LAST ATTEMPT 2007. PT HAS  
HX 2 ADMISSIONS, ONE AT BRV  
IN FEB 2020 FOR SI AND ONE  
HERE IN 2013. PT SAYS THAT  
HE HAS A REMOTE HISTORY OF  
VIOLENCE, LAST SPENDING  
TIME IN JC IN LATE 90'S FOR  
ASSAULT

HE HAS UNDERGONE  
COMPREHENSIVE  
PSYCHIATRIC EVALUATION  
AND THERAPEUTIC  
MANAGEMENT IN  
ACCORDANCE WITH THE PES  
GUIDELINES FOR PSYCHOSIS  
NOS. BASED ON HIS CLINICAL  
RESPONSE AND INFORMATION  
OBTAINED DURING THIS  
PERIOD OF OBSERVATION, IT  
HAS BEEN DETERMINED THAT  
HE WILL BE ADMITTED TO THE  
HOSPITAL FOR ONGOING  
MANAGEMENT

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 18 Mar 2021 22:22:55

**Generated On: 10 Jun 2021 09:20:38**

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

---

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

Yes ☒

No ☐

---

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

---



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication CAPLYTA

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

Dose per administration 42

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 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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)

370 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication HYDROXYZINE

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)

372 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 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"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH PREVENTIVE  
MEASURE

Dose per administration 81

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)

374 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

376 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication GARLIC

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

380 of 2247

EAB) (1725)

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication VITAMIN E

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 268

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication SAPHRIS

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

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)

386 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2013
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication TIMOLOL MALEATE

Prophylaxis Yes ☐  
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify GTTS

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

388 of 2247

EAB) (1725)

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		OU
Start date (dd MMM yyyy)		15 JUL 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐  
No ☒

Indication UNSPECIFIED ACUTE RENAL FAILURE

Dose per administration 650

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 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2015
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication RISPERIDONE

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOAFFECTIVE DISORDER,  
WORSENING

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)

392 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	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)	04 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication LAMICTAL

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

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

394 of 2247

EAB) (1725)

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	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)	30 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 DEC 2020	
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"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication LAMICTAL

Prophylaxis Yes ☐  
No ☒

Indication BI POLAR DISORDER

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

396 of 2247

EAB) (1725)

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication RISPERIDONE

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOAFFECTIVE DISORDER,  
WORSENING

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)

398 of 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

	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)	28 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)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

Name of Medication KILONOPIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY, NO GRADE CHANGE.  
ADDED TO CURRENT REGIMEN  
FOR ANXIETY

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 2247

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 19:07:58

Generated On: 10 Jun 2021 09:20:38

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

US3662181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Mar 2021 22:22:55

Generated On: 10 Jun 2021 09:20:38

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

**US3662181**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 10 Jun 2021 09:20:38**

---

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

---

US3662181

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:20:38

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 ☐

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

SAEID	USA-US088-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

SAEID	USA-US088-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:08
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

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

SAEID	USA-US088-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/JAN/2021 17:34
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



US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Mar 2021 22:22:56

Generated On: 10 Jun 2021 09:20:38

SAEID	USA-US088-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/FEB/2021 11:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3662181 (Prod: Cincinnati CRS)

**US3662181**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:20:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'US3662181'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 15:08:40

**US3662181**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:52:12

**US3662181**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 15:08:41

**US3662181**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	27 Oct 2020 15:52:12

**US3662181**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'SCRN'	System	27 Oct 2020 15:52:12

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 15:08:42



**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '61'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'YEARS'	System	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '61'	System	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Male (M)'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'I'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'I'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09



**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:20:38**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:53:09

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Oct 2020'	System	22 Oct 2020 16:48:04



**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2020'	System	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Amendment 4 (4)'	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:04

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 15:08:41

**US3662181**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:20:38**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'I'	System	22 Oct 2020 16:48:08



**US3662181**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	22 Oct 2020 16:48:08

**US3662181**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:20:38**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:53:43

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:55:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:55:46
Data point term sent to Coder	System	27 Oct 2020 15:54:54
User entered 'HYPERLIPIDEMIA, UNSPECIFIED'	Brenda Miller (b) (4)	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2015' reason for change: Data Entry Error	(b) (4)	
	MaKayla Bishop (b) (4)	23 Dec 2020 13:56:15
User entered '15 Jul 2020'	(b) (4)	
	Brenda Miller (b) (4)	27 Oct 2020 15:54:20
	(b) (4)	

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:54:20



**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2015'	System	23 Dec 2020 13:56:15
User entered 'Jul 2020'	System	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2015'	System	23 Dec 2020 13:56:15
User entered '2020'	System	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:54:20

**US3662181**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per MM, please confirm if this condition meets the EC #8 'Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:16
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Coagulation disorders congenital, PT: Von Willebrand's disease, LLT: Von Willebrand's factor deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:23:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:23:15
Data point term sent to Coder	System	24 Nov 2020 04:28:31
Query 'Per MM, please confirm if this condition meets the EC #8 'Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy'. ' answered with 'event term updated' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:46
Coding entries removed.	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:38
User entered 'Low von Willebrand factor' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:38
User opened query 'Per MM, please confirm if this condition meets the EC #8 'Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy'. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:17:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Coagulopathy, LLT: Defect coagulation (NOS) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:06:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:06:33
Data point term sent to Coder	System	27 Oct 2020 15:54:57
User entered 'COAGULATION DEFECT, UNSPECIFIED'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2015'	Brenda Miller (b) (4)	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:54:48



**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2015'	System	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2015'	System	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:54:48

**US3662181**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:56:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:56:35
Data point term sent to Coder	System	27 Oct 2020 15:55:59
User entered 'HYPERTENSION NEC'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2014'	Brenda Miller (b) (4)	27 Oct 2020 15:55:38



**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 15:56:34
User entered 'Yes (Y)' reason for change: Data Entry Error	System	27 Oct 2020 15:56:34
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Miller (b) (4)	27 Oct 2020 15:56:34
User entered empty.	(b) (4)	
	System	27 Oct 2020 15:55:38
	Brenda Miller (b) (4)	27 Oct 2020 15:55:38
	(b) (4)	

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2014'	System	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2014'	System	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:55:38

**US3662181**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:55:38



US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Unspecified glaucoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Oct 2020 15:57:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:57:39
Data point term sent to Coder	System	27 Oct 2020 15:57:04
User entered 'UNSPECIFIED GLAUCOMA'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2000'	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2000'	System	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2000'	System	27 Oct 2020 15:56:59



**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:56:59

**US3662181**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Endocrine disorders, HLT: Parathyroid gland disorders, HLT: Hyperparathyroid disorders, PT: Hyperparathyroidism, LLT: Hyperparathyroidism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Oct 2020 15:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:59:40
Data point term sent to Coder	System	27 Oct 2020 15:58:06
User entered 'HYPERPARATHYROIDISM'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1980'	Brenda Miller (b) (4)	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:57:24



**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1980'	System	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1980'	System	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:57:24

**US3662181**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar affective disorder, unspecified - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Oct 2020 21:35:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:35:34
Data point term sent to Coder	System	27 Oct 2020 15:58:13
User entered 'BIPOLAR AFFECTIVE DISORDER UNSPECIFIED'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1974'	Brenda Miller (b) (4)	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:57:46



**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1974'	System	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1974'	System	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:57:46

**US3662181**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
Data point term sent to Coder	System	27 Oct 2020 15:58:15
User entered 'GENERALIZED ANXIETY DISORDER'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1974'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09



**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1974'	System	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1974'	System	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:58:09

**US3662181**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:58:09



US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Oct 2020 17:14:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:14:23
Data point term sent to Coder	System	27 Oct 2020 15:59:21
User entered 'MAJOR DEPRESSIVE DISORDER RECUR EPIS MILD'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1974'	Brenda Miller (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1974'	System	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1974'	System	27 Oct 2020 15:58:37



**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:58:37

**US3662181**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Psychiatric disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:04:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:04:33
Data point term sent to Coder	System	27 Oct 2020 15:59:19
User entered 'SCHIZO-AFFECT SHIZO UNSPECIFIED CONDITION'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1974'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05



**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1974'	System	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1974'	System	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:59:05

**US3662181**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Unspecified anemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:34:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:34:00
Data point term sent to Coder	System	23 Feb 2021 15:33:43
User entered 'unspecified anemia'	Angela Snyder (b) (4)	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2015'	Angela Snyder (b) (4)	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Feb 2021 15:33:09



**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2015'	System	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2015'	System	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:33:09

**US3662181**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:33:09

US3662181

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 4 - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 09:52:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:52:16
Data point term sent to Coder	System	23 Feb 2021 15:34:44
User entered 'chronic kidney disease stg. IV'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 2015'	Angela Snyder (b) (4)	23 Feb 2021 15:34:29



**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 2015'	System	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2015'	System	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:34:29

**US3662181**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:34:29



US3662181

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Retention of urine - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 06:37:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 06:37:23
Data point term sent to Coder	System	23 Feb 2021 15:35:45
User entered 'unspecified retention of urine'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Jun 2006'	Angela Snyder (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jun 2006'	System	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2006'	System	23 Feb 2021 15:34:58



**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:34:58

**US3662181**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:34:58

US3662181

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms benign, HLT: Nervous system neoplasms benign NEC, PT: Brain neoplasm benign, LLT: Benign neoplasm of brain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Feb 2021 15:36:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:36:00
Data point term sent to Coder	System	23 Feb 2021 15:35:45
User entered 'benign neoplasm of brain'	Angela Snyder (b) (4)	23 Feb 2021 15:35:33
	(b) (4)	

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1993'	Angela Snyder (b) (4)	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:35:33



**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1993'	System	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1993'	System	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:35:33

**US3662181**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:35:33

US3662181

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Convulsions - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 09:06:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:06:15
Data point term sent to Coder	System	23 Feb 2021 15:36:46
User entered 'other convulsions'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '15 Jul 1993'	Angela Snyder (b) (4)	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Feb 2021 15:36:01



**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Jul 1993'	System	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '1993'	System	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:36:01

**US3662181**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	23 Feb 2021 15:36:01

US3662181

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as SOC: Psychiatric disorders, HLT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4)	01 Mar 2021 15:15:50
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4)	01 Mar 2021 15:15:50
Data point term sent to Coders System	System	01 Mar 2021 15:14:50
User entered 'suicidal ideation'	Angela Snyder (b) (4)	01 Mar 2021 15:14:44
	(b) (4)	

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10 Feb 2020'	Angela Snyder (b) (4)	01 Mar 2021 15:14:44



**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Angela Snyder (b) (4)	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'Feb 2020'	System	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '2020'	System	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	01 Mar 2021 15:14:44

**US3662181**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered empty.	System	01 Mar 2021 15:14:44



**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:35'	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '22 Oct 2020 11:35'	System	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '171.5' cm	(b) (4) Brenda Miller (b) (4)	27 Oct 2020 16:00:16
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:08

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '96.9' kg	(b) (4) Brenda Miller (b) (4)	27 Oct 2020 16:00:16
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:08

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered '32.94546'	System	27 Oct 2020 16:00:16
DataPoint set to visible.	System	22 Oct 2020 16:48:08

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'kg/m2'	System	27 Oct 2020 16:00:16
DataPoint set to visible.	System	22 Oct 2020 16:48:08



**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'bpm'	System	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'breaths/min'	System	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16



**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'mmHg'	System	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User entered 'mmHg'	System	27 Oct 2020 16:00:16

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57

**US3662181**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57

**US3662181**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:00:28

**US3662181**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:00:28

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24



**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

[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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24



US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'I'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24



US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:38

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)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:01:24

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:05

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:02:05

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:05

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'VISIT1'	System	27 Oct 2020 16:02:05



US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:45

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '117833'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:45

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:45

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:20:38**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	27 Oct 2020 16:02:34
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:04

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:35'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '22 Oct 2020 11:35'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.6' F	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '66'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'bpm'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'breaths/min'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '113'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '77'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '13:59'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '22 Oct 2020 13:59'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.8' F	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '67'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'bpm'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'breaths/min'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '130'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '86'	Brenda Miller (b) (4)	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	27 Oct 2020 16:04:30

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:04:36



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:04:36

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	(b) (4) MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '13:14'	MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '22 Oct 2020 13:14'	System	22 Oct 2020 17:17:48



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'ONCE'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:02

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:08:02

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:55'	Brenda Miller (b) (4)	27 Oct 2020 16:08:02

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '22 Oct 2020 11:55'	System	27 Oct 2020 16:08:02

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '22 Oct 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:08:19



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:50'	Brenda Miller (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '22 Oct 2020 11:50'	System	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:08:19

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered empty.	System	27 Oct 2020 16:08:19



**US3662181**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:24

**US3662181**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	27 Oct 2020 16:08:24

**US3662181**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered 'Yes (Y)'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered '97.8'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered 'No (N)'	System	22 Oct 2020 17:53:28

**US3662181**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered '22 Oct 2020 13:53'	System	22 Oct 2020 17:53:28

**US3662181**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered 'Yes (Y)'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered '97.6'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered 'No (N)'	System	23 Oct 2020 03:06:13

**US3662181**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered '22 Oct 2020 23:06'	System	23 Oct 2020 03:06:13

**US3662181**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:09:50', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered 'Yes (Y)'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:09:58', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered '97.6'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered 'No (N)'	System	24 Oct 2020 00:10:13

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:10', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered '23 Oct 2020 20:10'	System	24 Oct 2020 00:10:13

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered 'Yes (Y)'	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b' User entered '96.5'	System	24 Oct 2020 23:35:08
	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered 'No (N)'	System	24 Oct 2020 23:35:08

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b' User entered '24 Oct 2020 19:35'	System	24 Oct 2020 23:35:08
	System	24 Oct 2020 23:35:08

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:27:49', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered 'Yes (Y)'	System	26 Oct 2020 00:28:11



US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:27:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered '96.9'	System	26 Oct 2020 00:28:11

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered 'No (N)'	System	26 Oct 2020 00:28:11

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered '25 Oct 2020 20:28'	System	26 Oct 2020 00:28:11

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48



US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'None (1)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'No (N)'	System	22 Oct 2020 17:41:54

**US3662181**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'No (N)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:41:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'None (1)'	System	22 Oct 2020 17:41:54

**US3662181**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:41:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered '22 Oct 2020 13:41'	System	22 Oct 2020 17:41:54

**US3662181**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'None (1)'	System	23 Oct 2020 03:07:10

**US3662181**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:27', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'No (N)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'No (N)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:04', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'None (1)'	System	23 Oct 2020 03:07:10

**US3662181**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered '22 Oct 2020 23:07'	System	23 Oct 2020 03:07:10

**US3662181**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'None (1)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'No (N)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'No (N)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:34', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'None (1)'	System	24 Oct 2020 00:10:40

**US3662181**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered '23 Oct 2020 20:10'	System	24 Oct 2020 00:10:40

**US3662181**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'None (1)'	System	24 Oct 2020 23:37:06

**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'Yes (Y)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered '3'	System	24 Oct 2020 23:37:06

**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'No (N)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'None (1)'	System	24 Oct 2020 23:37:06

**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered '24 Oct 2020 19:37'	System	24 Oct 2020 23:37:06

**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:18', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'None (1)'	System	26 Oct 2020 00:29:23

**US3662181**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:24', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'No (N)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:45', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'No (N)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'None (1)'	System	26 Oct 2020 00:29:23

**US3662181**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered '25 Oct 2020 20:29'	System	26 Oct 2020 00:29:23

**US3662181**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



**US3662181**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48



**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:13', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'No (N)'	System	22 Oct 2020 17:42:34

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered '22 Oct 2020 13:42'	System	22 Oct 2020 17:42:34



**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51



**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'No (N)'	System	23 Oct 2020 03:07:51

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered '22 Oct 2020 23:07'	System	23 Oct 2020 03:07:51

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:50', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'No (N)'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered '23 Oct 2020 20:11'	System	24 Oct 2020 00:11:14

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'No (N)'	System	24 Oct 2020 23:37:39



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered '24 Oct 2020 19:37'	System	24 Oct 2020 23:37:39

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:27', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'No (N)'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:30:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered '25 Oct 2020 20:30'	System	26 Oct 2020 00:30:02

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



**US3662181**

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

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

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:20:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48



**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:20:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22



US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:20:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

US3662181

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

**US3662181**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 14:27:24
User entered 'Yes (Y)'	System	05 Nov 2020 14:26:29
	Brenda Miller (b) (4)	05 Nov 2020 14:26:29
	(b) (4)	



**US3662181**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	05 Nov 2020 14:27:24
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	05 Nov 2020 14:26:29
	(b) (4)	

**US3662181**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Not Made (CONTACT NOT MADE)'	Brenda Miller (b) (4)	05 Nov 2020 14:26:29

**US3662181**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'CALLED AND TEXTED PARTICIPANT- LEFT MESSAGE. PHONE WENT STRAIGHT TO VOICE MAIL'	Brenda Miller (b) (4)	05 Nov 2020 14:26:29

**US3662181**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:09:13

**US3662181**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	08 Nov 2020 17:09:13

**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:09:30

**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '05 Nov 2020'	Brenda Miller (b) (4)	08 Nov 2020 17:09:30

**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	08 Nov 2020 17:09:30



**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 17:09:30

**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:09:37

**US3662181**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	08 Nov 2020 17:09:37

**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	13 Nov 2020 15:32:04

**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Nov 2020'	Brenda Miller (b) (4)	13 Nov 2020 15:32:04

**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	13 Nov 2020 15:32:04

**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	13 Nov 2020 15:32:04

**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	13 Nov 2020 15:32:10



**US3662181**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	13 Nov 2020 15:32:10

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:26:37

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:26:37

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	19 Nov 2020 19:26:37

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'VISIT2'	System	19 Nov 2020 19:26:37

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '09:52'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '19 Nov 2020 09:52'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.8' F	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '70'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'bpm'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'breaths/min'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '119'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '78'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:10'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.9' F	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '63'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'bpm'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'breaths/min'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '124'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '80'	Brenda Miller (b) (4)	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	19 Nov 2020 19:28:34

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:28:55

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:28:55

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	(b) (4) MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:39'	MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '19 Nov 2020 10:39'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'ONCE'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:29:28

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:29:28

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:15'	Brenda Miller (b) (4)	19 Nov 2020 19:29:28

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '19 Nov 2020 10:15'	System	19 Nov 2020 19:29:28

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Nov 2020'	Brenda Miller (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	19 Nov 2020 19:29:47



**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:10'	Brenda Miller (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '19 Nov 2020 10:10'	System	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Brenda Miller (b) (4)	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered empty.	System	19 Nov 2020 19:29:47

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	19 Nov 2020 19:29:54

**US3662181**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '1'	System	19 Nov 2020 19:29:54



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered 'Yes (Y)'	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d' User entered '97.9'	System	19 Nov 2020 16:10:03
	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:54', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered 'No (N)'	System	19 Nov 2020 16:10:03

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered '19 Nov 2020 11:09'	System	19 Nov 2020 16:10:03

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:25:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered 'Yes (Y)'	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:25:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a' User entered '98.3'	System	20 Nov 2020 03:26:08
	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered 'No (N)'	System	20 Nov 2020 03:26:08

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:04', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a' User entered '19 Nov 2020 22:26'	System	20 Nov 2020 03:26:08
	System	20 Nov 2020 03:26:08

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered 'Yes (Y)'	System	21 Nov 2020 00:18:43



US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered '98.2'	System	21 Nov 2020 00:18:43

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered 'No (N)'	System	21 Nov 2020 00:18:43

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered '20 Nov 2020 19:15'	System	21 Nov 2020 00:18:43

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:23', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered 'Yes (Y)'	System	22 Nov 2020 00:18:38

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered '97.3'	System	22 Nov 2020 00:18:38



US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered 'No (N)'	System	22 Nov 2020 00:18:38

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered '21 Nov 2020 19:18'	System	22 Nov 2020 00:18:38

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:08:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered 'Yes (Y)'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:07', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered '98.3'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered 'No (N)'	System	23 Nov 2020 01:09:18



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered '22 Nov 2020 20:09'	System	23 Nov 2020 01:09:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered 'Yes (Y)'	System	24 Nov 2020 01:42:41

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered '97.9'	System	24 Nov 2020 01:42:41

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered 'No (N)'	System	24 Nov 2020 01:42:41

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered '23 Nov 2020 20:42'	System	24 Nov 2020 01:42:41



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e74d0bf8-ff41-440d-8a71-1fea1f31629b'	System	25 Nov 2020 14:26:21
User entered 'Yes (Y)'	System	25 Nov 2020 14:26:21

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:13', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e74d0bf8-ff41-440d-8a71-1fea1f31629b'	System	25 Nov 2020 14:26:21
User entered '98.2'	System	25 Nov 2020 14:26:21

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e74d0bf8-ff41-440d-8a71-1fea1f31629b'	System	25 Nov 2020 14:26:21
User entered 'No (N)'	System	25 Nov 2020 14:26:21

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e74d0bf8-ff41-440d-8a71-1fea1f31629b'	System	25 Nov 2020 14:26:21
User entered '25 Nov 2020 09:26'	System	25 Nov 2020 14:26:21

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b64c611-99de-4eed-a144-07a588ee6bcf'	System	26 Nov 2020 06:50:28
User entered 'Yes (Y)'	System	26 Nov 2020 06:50:28

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b64c611-99de-4eed-a144-07a588ee6bcf'	System	26 Nov 2020 06:50:28
User entered '97.2'	System	26 Nov 2020 06:50:28

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b64c611-99de-4eed-a144-07a588ee6bcf'	System	26 Nov 2020 06:50:28
User entered 'No (N)'	System	26 Nov 2020 06:50:28

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b64c611-99de-4eed-a144-07a588ee6bcf'	System	26 Nov 2020 06:50:28
User entered '26 Nov 2020 01:50'	System	26 Nov 2020 06:50:28

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'None (1)'	System	19 Nov 2020 16:10:32

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'No (N)'	System	19 Nov 2020 16:10:32

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'No (N)'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'None (1)'	System	19 Nov 2020 16:10:32

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 16:10:32

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'None (1)'	System	20 Nov 2020 03:26:46

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'No (N)'	System	20 Nov 2020 03:26:46

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'No (N)'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'None (1)'	System	20 Nov 2020 03:26:46

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered '19 Nov 2020 22:26'	System	20 Nov 2020 03:26:46

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'None (1)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'No (N)'	System	21 Nov 2020 00:18:44

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'No (N)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:23', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'None (1)'	System	21 Nov 2020 00:18:44

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f' User entered '20 Nov 2020 19:16'	System	21 Nov 2020 00:18:44
	System	21 Nov 2020 00:18:44

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'None (1)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'No (N)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:49', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'No (N)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'None (1)'	System	22 Nov 2020 00:19:11

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered '21 Nov 2020 19:19'	System	22 Nov 2020 00:19:11

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'None (1)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:29', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'No (N)'	System	23 Nov 2020 01:10:03

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'No (N)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'None (1)'	System	23 Nov 2020 01:10:03

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered '22 Nov 2020 20:10'	System	23 Nov 2020 01:10:03

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'None (1)'	System	24 Nov 2020 01:43:07

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'No (N)'	System	24 Nov 2020 01:43:07

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'No (N)'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'None (1)'	System	24 Nov 2020 01:43:07

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered '23 Nov 2020 20:43'	System	24 Nov 2020 01:43:07

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '1f2effc5-86d7-493e-a050-de9cd10cdaf1'	System	25 Nov 2020 14:26:51
User entered 'None (1)'	System	25 Nov 2020 14:26:51

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:28', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '1f2effc5-86d7-493e-a050-de9cd10cdaf1'	System	25 Nov 2020 14:26:51
User entered 'No (N)'	System	25 Nov 2020 14:26:51

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '1f2effc5-86d7-493e-a050-de9cd10cdaf1'	System	25 Nov 2020 14:26:51
User entered 'No (N)'	System	25 Nov 2020 14:26:51

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '1f2effc5-86d7-493e-a050-de9cd10cdaf1'	System	25 Nov 2020 14:26:51
User entered 'None (1)'	System	25 Nov 2020 14:26:51

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:49', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '1f2effc5-86d7-493e-a050-de9cd10cdaf1'	System	25 Nov 2020 14:26:51
User entered '25 Nov 2020 09:26'	System	25 Nov 2020 14:26:51

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:34', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7b7b293-6b78-44af-9de7-7049e75d61d7'	System	26 Nov 2020 06:51:11
User entered 'None (1)'	System	26 Nov 2020 06:51:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7b7b293-6b78-44af-9de7-7049e75d61d7'	System	26 Nov 2020 06:51:11
User entered 'No (N)'	System	26 Nov 2020 06:51:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:50:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7b7b293-6b78-44af-9de7-7049e75d61d7'	System	26 Nov 2020 06:51:11
User entered 'No (N)'	System	26 Nov 2020 06:51:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7b7b293-6b78-44af-9de7-7049e75d61d7'	System	26 Nov 2020 06:51:11
User entered 'None (1)'	System	26 Nov 2020 06:51:11

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7b7b293-6b78-44af-9de7-7049e75d61d7'	System	26 Nov 2020 06:51:11
User entered '26 Nov 2020 01:51'	System	26 Nov 2020 06:51:11

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:53', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'No (N)'	System	19 Nov 2020 16:11:00



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 16:11:00

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'No (N)'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered '19 Nov 2020 22:27'	System	20 Nov 2020 03:27:16

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:40', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:45', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'No (N)'	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:17:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011' User entered '20 Nov 2020 19:17'	System	21 Nov 2020 00:18:45
	System	21 Nov 2020 00:18:45

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:40', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered 'None (0)'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50



US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'No (N)'	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f' User entered '21 Nov 2020 19:19'	System	22 Nov 2020 00:19:50
	System	22 Nov 2020 00:19:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:29', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'No (N)'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered '22 Nov 2020 20:10'	System	23 Nov 2020 01:10:42

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:10', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:28', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'No (N)'	System	24 Nov 2020 01:43:30

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b' User entered '23 Nov 2020 20:43'	System	24 Nov 2020 01:43:30
	System	24 Nov 2020 01:43:30



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:53', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:26:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:27:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:27:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:27:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'None (0)'	System	25 Nov 2020 14:27:18

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:27:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered 'No (N)'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-25T09:27:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '84647ed2-322f-4daf-9de5-c56bc0b76d8c'	System	25 Nov 2020 14:27:18
User entered '25 Nov 2020 09:27'	System	25 Nov 2020 14:27:18

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39



**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:27', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'None (0)'	System	26 Nov 2020 06:51:39

US3662181

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:20:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered 'No (N)'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-26T01:51:34', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '420a5e4d-53c1-40df-b771-6cc0f33bca97'	System	26 Nov 2020 06:51:39
User entered '26 Nov 2020 01:51'	System	26 Nov 2020 06:51:39

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

**US3662181**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:20:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:22
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50



**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Nov 2020 16:55:14

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '27 Nov 2020'	Angela Snyder (b) (4)	30 Nov 2020 16:55:14

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	30 Nov 2020 16:55:14

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	30 Nov 2020 16:55:14

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Nov 2020 16:55:20

**US3662181**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	30 Nov 2020 16:55:20

**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	03 Dec 2020 17:32:28

**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '3 Dec 2020'	Angela Snyder (b) (4)	03 Dec 2020 17:32:28



**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	03 Dec 2020 17:32:28

**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	03 Dec 2020 17:32:28

**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	03 Dec 2020 17:32:33

**US3662181**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	03 Dec 2020 17:32:33

**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Dec 2020 18:00:57

**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10 Dec 2020'	Angela Snyder (b) (4)	10 Dec 2020 18:00:57

**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	10 Dec 2020 18:00:57

**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	10 Dec 2020 18:00:57



**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Dec 2020 18:01:08

**US3662181**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	10 Dec 2020 18:01:08

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Dec 2020 17:48:09

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '17 Dec 2020'	(b) (4) Angela Snyder (b) (4)	18 Dec 2020 17:48:09

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	18 Dec 2020 17:48:09

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'VISIT3'	System	18 Dec 2020 17:48:09

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '17 Dec 2020'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21



**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:14'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '17 Dec 2020 10:14'	System	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.2' F	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'INFRARED THERMOMETER'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '65'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'bpm'	System	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21



**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'breaths/min'	System	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '140'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '85'	Angela Snyder (b) (4)	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'mmHg'	System	18 Dec 2020 17:49:21

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Dec 2020 17:49:30



**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '17 Dec 2020'	Angela Snyder (b) (4)	18 Dec 2020 17:49:30

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Dec 2020 17:49:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '17 Dec 2020'	Angela Snyder (b) (4)	18 Dec 2020 17:49:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:20'	Angela Snyder (b) (4)	18 Dec 2020 17:49:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered '17 Dec 2020 10:20'	System	18 Dec 2020 17:49:57

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Dec 2020 17:50:02

**US3662181**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	18 Dec 2020 17:50:02

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2020-12-19T00:25:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '93916e2b-bedf-46f1-9e4c-be29e9540228'	System	19 Dec 2020 05:25:32
User entered 'No (N)'	System	19 Dec 2020 05:25:32

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2020-12-19T00:25:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '93916e2b-bedf-46f1-9e4c-be29e9540228'	System	19 Dec 2020 05:25:32
User entered 'No (N)'	System	19 Dec 2020 05:25:32

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-12-19T00:25:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '93916e2b-bedf-46f1-9e4c-be29e9540228' User entered '19 Dec 2020 00:25:30'	System	19 Dec 2020 05:25:32
	System	19 Dec 2020 05:25:32

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-01-13T20:39:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5591dde2-cc9b-488a-97de-5a98f8f16865'	System	14 Jan 2021 01:39:58
User entered 'No (N)'	System	14 Jan 2021 01:39:58

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-01-13T20:39:53', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5591dde2-cc9b-488a-97de-5a98f8f16865'	System	14 Jan 2021 01:39:58
User entered 'No (N)'	System	14 Jan 2021 01:39:58

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-01-13T20:39:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5591dde2-cc9b-488a-97de-5a98f8f16865'	System	14 Jan 2021 01:39:58
User entered '13 Jan 2021 20:39:57'	System	14 Jan 2021 01:39:58

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-01-20T12:04:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2b2bc5c7-9336-455a-8944-ad35686d7895'	System	20 Jan 2021 17:05:15
User entered 'No (N)'	System	20 Jan 2021 17:05:15

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-01-20T12:05:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2b2bc5c7-9336-455a-8944-ad35686d7895'	System	20 Jan 2021 17:05:15
User entered 'No (N)'	System	20 Jan 2021 17:05:15

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-01-20T12:05:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2b2bc5c7-9336-455a-8944-ad35686d7895'	System	20 Jan 2021 17:05:15
User entered '20 Jan 2021 12:05:09'	System	20 Jan 2021 17:05:15

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-01-27T11:32:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5ba11357-78f8-4ca1-b5b7-135d259ae40f'	System	27 Jan 2021 16:32:17
User entered 'No (N)'	System	27 Jan 2021 16:32:17

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-01-27T11:32:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5ba11357-78f8-4ca1-b5b7-135d259ae40f'	System	27 Jan 2021 16:32:17
User entered 'No (N)'	System	27 Jan 2021 16:32:17

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-01-27T11:32:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5ba11357-78f8-4ca1-b5b7-135d259ae40f' User entered '27 Jan 2021 11:32:12'	System	27 Jan 2021 16:32:17

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-02-03T14:41:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b4538b9-c7b8-4631-8431-a8b0674d995d'	System	03 Feb 2021 19:41:28
User entered 'No (N)'	System	03 Feb 2021 19:41:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-02-03T14:41:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b4538b9-c7b8-4631-8431-a8b0674d995d'	System	03 Feb 2021 19:41:28
User entered 'No (N)'	System	03 Feb 2021 19:41:28



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-03T14:41:24', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7b4538b9-c7b8-4631-8431-a8b0674d995d'	System	03 Feb 2021 19:41:28
User entered '03 Feb 2021 14:41:24'	System	03 Feb 2021 19:41:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-02-13T20:13:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ddc49051-6042-48e2-be05-6f1b12e4ae7d'	System	14 Feb 2021 01:13:45
User entered 'No (N)'	System	14 Feb 2021 01:13:45



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-02-13T20:13:34', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ddc49051-6042-48e2-be05-6f1b12e4ae7d'	System	14 Feb 2021 01:13:45
User entered 'No (N)'	System	14 Feb 2021 01:13:45

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-13T20:13:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ddc49051-6042-48e2-be05-6f1b12e4ae7d'	System	14 Feb 2021 01:13:45
User entered '13 Feb 2021 20:13:38'	System	14 Feb 2021 01:13:45

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-02-20T14:29:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '9942aed5-6e41-41ba-8855-611fc72a8f17'	System	20 Feb 2021 19:29:50
User entered 'No (N)'	System	20 Feb 2021 19:29:50

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-02-20T14:29:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '9942aed5-6e41-41ba-8855-611fc72a8f17'	System	20 Feb 2021 19:29:50
User entered 'No (N)'	System	20 Feb 2021 19:29:50

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-20T14:29:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '9942aed5-6e41-41ba-8855-611fc72a8f17' User entered '20 Feb 2021 14:29:47'	System	20 Feb 2021 19:29:50
	System	20 Feb 2021 19:29:50



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-02-27T20:22:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'c669f5f2-0964-4cdc-b04a-fa2bcbb33c18'	System	28 Feb 2021 01:22:57
User entered 'No (N)'	System	28 Feb 2021 01:22:57

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-02-27T20:22:50', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'c669f5f2-0964-4cdc-b04a-fa2bcbb33c18'	System	28 Feb 2021 01:22:57
User entered 'No (N)'	System	28 Feb 2021 01:22:57

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-27T20:22:53', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'c669f5f2-0964-4cdc-b04a-fa2bcbb33c18' User entered '27 Feb 2021 20:22:53'	System	28 Feb 2021 01:22:57
	System	28 Feb 2021 01:22:57

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-03-06T00:02:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2911cb9f-7375-453e-977f-3756eefc65b6'	System	06 Mar 2021 05:05:29
User entered 'No (N)'	System	06 Mar 2021 05:05:29

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-03-06T00:03:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2911cb9f-7375-453e-977f-3756eefc65b6'	System	06 Mar 2021 05:05:29
User entered 'No (N)'	System	06 Mar 2021 05:05:29

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-03-06T00:03:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '2911cb9f-7375-453e-977f-3756eefc65b6'	System	06 Mar 2021 05:05:29
User entered '06 Mar 2021 00:03:05'	System	06 Mar 2021 05:05:29

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-03-13T18:55:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e4b03367-558d-4aeb-bd03-7d5fe83aba25'	System	13 Mar 2021 23:56:04
User entered 'No (N)'	System	13 Mar 2021 23:56:04



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-03-13T18:55:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e4b03367-558d-4aeb-bd03-7d5fe83aba25'	System	13 Mar 2021 23:56:04
User entered 'No (N)'	System	13 Mar 2021 23:56:04

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-03-13T18:55:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e4b03367-558d-4aeb-bd03-7d5fe83aba25'	System	13 Mar 2021 23:56:04
User entered '13 Mar 2021 18:55:59'	System	13 Mar 2021 23:56:04

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-03-20T12:57:23', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '91e700bb-2134-457d-9ad9-9f62ae546bab'	System	20 Mar 2021 16:57:35
User entered 'No (N)'	System	20 Mar 2021 16:57:35

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-03-20T12:57:28', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '91e700bb-2134-457d-9ad9-9f62ae546bab'	System	20 Mar 2021 16:57:35
User entered 'No (N)'	System	20 Mar 2021 16:57:35

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-03-20T12:57:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '91e700bb-2134-457d-9ad9-9f62ae546bab' User entered '20 Mar 2021 12:57:32'	System	20 Mar 2021 16:57:35
	System	20 Mar 2021 16:57:35



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-03-27T12:28:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '21372502-7f02-4f40-8e22-bb57af001c68'	System	27 Mar 2021 16:28:28
User entered 'No (N)'	System	27 Mar 2021 16:28:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-03-27T12:28:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '21372502-7f02-4f40-8e22-bb57af001c68'	System	27 Mar 2021 16:28:28
User entered 'No (N)'	System	27 Mar 2021 16:28:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-03-27T12:28:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '21372502-7f02-4f40-8e22-bb57af001c68'	System	27 Mar 2021 16:28:28
User entered '27 Mar 2021 12:28:25'	System	27 Mar 2021 16:28:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-04-12T16:31:18', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'f7a9c94d-68ea-4a1b-b680-26163e3582be'	System	12 Apr 2021 20:31:28
User entered 'No (N)'	System	12 Apr 2021 20:31:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-04-12T16:31:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'f7a9c94d-68ea-4a1b-b680-26163e3582be'	System	12 Apr 2021 20:31:28
User entered 'No (N)'	System	12 Apr 2021 20:31:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-04-12T16:31:24', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'f7a9c94d-68ea-4a1b-b680-26163e3582be' User entered '12 Apr 2021 16:31:24'	System	12 Apr 2021 20:31:28
	System	12 Apr 2021 20:31:28

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-04-25T10:41:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '14467648-0aff-4311-9c2a-64b327e86f37'	System	25 Apr 2021 14:42:01
User entered 'No (N)'	System	25 Apr 2021 14:42:01

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-04-25T10:41:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '14467648-0aff-4311-9c2a-64b327e86f37'	System	25 Apr 2021 14:42:01
User entered 'No (N)'	System	25 Apr 2021 14:42:01

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-04-25T10:41:54', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '14467648-0aff-4311-9c2a-64b327e86f37'	System	25 Apr 2021 14:42:01
User entered '25 Apr 2021 10:41:54'	System	25 Apr 2021 14:42:01



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[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 (d1dbddc93e6bc7ef)', Time: '2021-05-01T17:13:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b910e5cb-3d91-4d90-891f-2696c891c4a7'	System	01 May 2021 21:13:50
User entered 'No (N)'	System	01 May 2021 21:13:50

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

Have you been exposed to someone with 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 (d1dbddc93e6bc7ef)', Time: '2021-05-01T17:13:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b910e5cb-3d91-4d90-891f-2696c891c4a7'	System	01 May 2021 21:13:50
User entered 'No (N)'	System	01 May 2021 21:13:50

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-05-01T17:13:40', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b910e5cb-3d91-4d90-891f-2696c891c4a7'	System	01 May 2021 21:13:50
User entered '01 May 2021 17:13:40'	System	01 May 2021 21:13:50

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:29:36



**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

**US3662181**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:20:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:20:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:49:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-27T20:23:18', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'fd130f03-3d87-49f4-ac23-0f2b4befb17a'	System	28 Feb 2021 01:23:30
User entered 'No (N)'	System	28 Feb 2021 01:23:30

**US3662181**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:49:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2021-02-27T20:23:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'fd130f03-3d87-49f4-ac23-0f2b4befb17a'	System	28 Feb 2021 01:23:30
User entered '27 Feb 2021 20:23:26'	System	28 Feb 2021 01:23:30

**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 13:37:31

**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '14 Jan 2021'	Angela Snyder (b) (4)	29 Jan 2021 13:37:31

**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	29 Jan 2021 13:37:31

**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	29 Jan 2021 13:37:31



**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 13:37:36

**US3662181**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:40:57
User entered 'I'	System	29 Jan 2021 13:37:36

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Feb 2021 15:20:36

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Feb 2021'	Angela Snyder (b) (4)	19 Feb 2021 15:20:36

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	19 Feb 2021 15:20:36

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	19 Feb 2021 15:20:36

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Feb 2021 15:20:41

**US3662181**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:26
User entered 'I'	System	19 Feb 2021 15:20:41



**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:18

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered '19 Mar 2021'	Angela Snyder (b) (4)	23 Mar 2021 15:44:18

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:18

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered empty.	Angela Snyder (b) (4)	23 Mar 2021 15:44:18

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:24

**US3662181**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:35
User entered 'I'	System	23 Mar 2021 15:44:24

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 14:35:19
	(b) (4)	

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:43:14
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	20 Apr 2021 14:17:29
	(b) (4)	
User entered '20 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 14:17:29
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '15 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 14:35:19
	(b) (4)	



**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Apr 2021 14:35:19

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 14:35:19
	(b) (4)	

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 14:35:25
	(b) (4)	

**US3662181**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 14:35:25

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:38:41

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	Angela Snyder (b) (4)	16 Feb 2021 15:38:41

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[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 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	16 Feb 2021 15:38:41

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'UNBLND_DECIDE'	System	16 Feb 2021 15:38:41



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[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 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:57:54

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

US3662181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:20:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 07:29:28
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 11:57:04
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 11:56:20
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 11:56:20
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:23:16
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:23:01
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:57:54

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '1'	System	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'I'	System	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '171.45' cm	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '99.51' kg	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '33.85258'	System	16 Feb 2021 15:41:10
DataPoint set to visible.	System	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '171.45' cm	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '99.51' kg	Angela Snyder (b) (4)	16 Feb 2021 15:41:10



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '33.85258'	System	16 Feb 2021 15:41:10
DataPoint set to visible.	System	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '09:32'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Feb 2021 09:32'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.9' F	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'infrared thermometer'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '68'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'bpm'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'breaths/min'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '146'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '89'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '171.45' cm	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '99.51' kg	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:20:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '33.85258'	System	16 Feb 2021 15:41:10
DataPoint set to visible.	System	12 Feb 2021 14:49:22

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:35'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Feb 2021 10:35'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '97.9' F	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'infrared thermometer'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '64'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'bpm'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'breaths/min'	System	16 Feb 2021 15:41:10



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '130'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '86'	Angela Snyder (b) (4)	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	16 Feb 2021 15:41:10

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:17

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	Angela Snyder (b) (4)	16 Feb 2021 15:41:17

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

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 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mRNA-1273'	System	12 Feb 2021 15:06:39
DataPoint set to visible.	System	12 Feb 2021 14:49:22

US3662181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:05'	MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Feb 2021 10:05'	System	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'ONCE'	System	12 Feb 2021 15:06:39

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 15:06:39



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:38

US3662181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' answered with 'sample is reported in Preclarus. Accession Number: 1F60NCB' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:13:36
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '12 Feb 2021'	michelle saemann (b) (4) (b) (4)	25 Feb 2021 19:38:52
	(b) (4), (b) (6)	25 Feb 2021 16:59:31
	Angela Snyder (b) (4) (b) (4)	16 Feb 2021 15:41:38

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '09:45'	Angela Snyder (b) (4)	16 Feb 2021 15:41:38

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Feb 2021 09:45'	System	16 Feb 2021 15:41:38

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:51

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Feb 2021'	Angela Snyder (b) (4)	16 Feb 2021 15:41:51

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:20:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '09:42'	Angela Snyder (b) (4)	16 Feb 2021 15:41:51

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:20:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Feb 2021 09:42'	System	16 Feb 2021 15:41:51



**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Feb 2021 15:41:57

**US3662181**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'I'	System	16 Feb 2021 15:41:57

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Feb 2021 15:20:55

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '19 Feb 2021'	Angela Snyder (b) (4)	19 Feb 2021 15:20:55

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	19 Feb 2021 15:20:55

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	Angela Snyder (b) (4)	19 Feb 2021 15:20:55

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Feb 2021 15:21:00

**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User entered 'I'	System	19 Feb 2021 15:21:00



**US3662181**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User entered '1'	System	19 Feb 2021 15:21:00
DataPoint set to visible.	System	19 Feb 2021 15:21:00

**US3662181**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Mar 2021 17:44:29

**US3662181**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Mar 2021'	Angela Snyder (b) (4)	12 Mar 2021 17:44:29

**US3662181**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[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 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	12 Mar 2021 17:44:29

**US3662181**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'OLD29'	System	12 Mar 2021 17:44:29

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Mar 2021'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06



**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '09:57'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Mar 2021 09:57'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '98.3' F	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'infrared thermometer'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '70'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'bpm'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06



**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'breaths/min'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '136'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '89'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Mar 2021'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06



**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '11:07'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Mar 2021 11:07'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '98.3' F	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Other (Other)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'infrared thermometer'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '69'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'bpm'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '16'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06



**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'breaths/min'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '131'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '89'	Angela Snyder (b) (4)	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mmHg'	System	12 Mar 2021 17:46:06

**US3662181**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:19

**US3662181**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Mar 2021'	Angela Snyder (b) (4)	12 Mar 2021 17:46:19

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43



**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

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 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered empty.	MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'mRNA-1273'	System	12 Mar 2021 15:35:43
DataPoint set to visible.	System	19 Feb 2021 15:21:00

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '12 Mar 2021'	MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered '10:35'	(b) (4) MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered '12 Mar 2021 10:35'	System	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'ONCE'	System	12 Mar 2021 15:35:43



**US3662181**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:20:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 15:35:43

**US3662181**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Mar 2021 17:46:33

**US3662181**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'I'	System	12 Mar 2021 17:46:33

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:36

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered '19 Mar 2021'	Angela Snyder (b) (4)	23 Mar 2021 15:44:36

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:36

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:20:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered empty.	Angela Snyder (b) (4)	23 Mar 2021 15:44:36

**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:59:04
User entered 'Yes (Y)'	Angela Snyder (b) (4)	23 Mar 2021 15:44:42



**US3662181**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:20:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:14
User entered 'I'	System	23 Mar 2021 15:44:42

**US3662181**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Apr 2021 18:05:03
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	09 Apr 2021 18:05:03
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'Clinic (Clinic)'	(b) (4) Angela Snyder (b) (4) (b) (4)	09 Apr 2021 18:05:03

**US3662181**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:20:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	09 Apr 2021 18:05:03

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

*Date of assessment (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '10:27'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	



**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 10:27'	System	09 Apr 2021 18:05:54

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '98.2' F	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Other (Other)'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'infrared thermometer'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '76'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 18:05:54

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '16'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 18:05:54



**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '118'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:05:54

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '82'	Angela Snyder (b) (4)	09 Apr 2021 18:05:54
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:20:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:05:54

**US3662181**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Apr 2021 18:06:06
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:20:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	09 Apr 2021 18:06:06
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Apr 2021 18:06:23
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	09 Apr 2021 18:06:23
	(b) (4)	



**US3662181**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '10:39'	Angela Snyder (b) (4)	09 Apr 2021 18:06:23
	(b) (4)	

**US3662181**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:20:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 10:39'	System	09 Apr 2021 18:06:23

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:20:38**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:49:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:24
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:48:57

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:39
User entered		
'USA-US088-2020-mRNA-1273-P301000003'	System	04 Nov 2020 15:07:33
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:07:33

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:11:46
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 00:24:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 00:24:57
User closed query 'Please request medical records from facility again. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 19:05:29
User closed query 'Per CDM Re-Query: Please confirm if this is related to Med Hx reported (Worsening), or if this is a different AE. Thank you ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:31:46
Data point term sent to Coder	System	01 Feb 2021 17:24:46
Query 'Per CDM Re-Query: Please confirm if this is related to Med Hx reported (Worsening), or if this is a different AE. Thank you ' answered with 'updated' (Site from DM).	michelle saemann (b) (4)	01 Feb 2021 17:24:37
User entered 'SCHIZOAFFECTIVE DISORDERS, worsening' reason for change: Data Entry Error	michelle saemann (b) (4)	01 Feb 2021 17:24:29
User opened query 'Per CDM Re-Query: Please confirm if this is related to Med Hx reported (Worsening), or if this is a different AE. Thank you ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:22:14
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of SCHIZO-AFFECT SHIZO, MAJOR DEPRESSIVE, or BIPOLAR noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:22:14
Data point term sent to Coder	System	25 Jan 2021 14:42:35

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm if this AE is a worsening of SCHIZO-AFFECT SHIZO, MAJOR DEPRESSIVE, or BIPOLAR noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'completed. ' (Site from DM). DataPoint Un-verified.	MaKayla Bishop (b) (4) (b) (4)	25 Jan 2021 14:42:11
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	25 Jan 2021 14:42:01
User entered 'Schizoaffective disorders with delusions' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	25 Jan 2021 14:42:01
Query 'Please request medical records from facility again. Thank you.' answered with 'medical records obtained. ' (Site from CRA).	MaKayla Bishop (b) (4) (b) (4)	25 Jan 2021 14:41:30
User opened query 'Please request medical records from facility again. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 17:32:14
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of SCHIZO-AFFECT SHIZO, MAJOR DEPRESSIVE, or BIPOLAR noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:20:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Psychotic disorder NEC, PT: Psychotic disorder, LLT: Unspecified psychosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:23
Data point term sent to Coder	System	03 Nov 2020 14:58:16
User entered 'Psychosis, unspecified'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16



**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '26 Oct 2020'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '30 Oct 2020'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:57:16



**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'I'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:22:30
Query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' answered with 'Date entered correct per source document' (Site from Safety).	Brenda Miller (b) (4) (b) (4)	23 Nov 2020 13:30:34
User opened query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:01
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '26 Oct 2020'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '30 Oct 2020'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16



**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:51:08
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'PT. DID RECEIVE 2ND IP DOSE. SEE DAY 29 INFORMATION. ' (Site from Safety).	michelle saemann (b) (4) (b) (4)	08 Dec 2020 14:45:05
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:10:38
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:57:40
User entered 'None (NONE)' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:40
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:57:16
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

None

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM). Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'no con med/ no con proc for this treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:29
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	25 Jan 2021 14:42:48
DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 05:20:31
User entered 'I'	(b) (4), (b) (6) michelle saemann (b) (4) (b) (4)	09 Nov 2020 17:06:06 03 Nov 2020 14:57:16



**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per DM CLR: Narrative = THERAPEUTIC MANAGEMENT IN ACCORDANCE WITH THE PES GUIDELINES FOR PSYCHOSIS. However, this is not recorded in the ConProc or ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:59:57
User closed query 'Per DM CLR: Narrative = PARANOIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:59:46
User closed query 'Per DM CLR: Narrative = PT HAS APPROX 4 SUICIDE ATTEMPTS IN HIS HISTORY, INCLUDING (b) (6) (b) (6). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:59:36
User closed query 'Per DM CLR: Narrative = PT HAS HX 2 ADMISSIONS, ONE AT BRV IN FEB 2020 FOR SI AND ONE HERE IN 2013. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:58:31
Query 'Per DM CLR: Narrative = THERAPEUTIC MANAGEMENT IN ACCORDANCE WITH THE PES GUIDELINES FOR PSYCHOSIS. However, this is not recorded in the ConProc or ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'no meds given in PES all meds reflected in log.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Mar 2021 14:09:17

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = PT HAS HX 2 ADMISSIONS, ONE AT BRV IN FEB 2020 FOR SI AND ONE HERE IN 2013. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Log Updated' (Site from DM).	MaKayla Bishop (b) (4)	01 Mar 2021 14:08:54
Query 'Per DM CLR: Narrative = PT HAS APPROX 4 SUICIDE ATTEMPTS IN HIS HISTORY, INCLUDING (b) (6). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'MH Added' (Site from DM).	MaKayla Bishop (b) (4)	01 Mar 2021 14:08:44
Query 'Per DM CLR: Narrative = PARANOIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'MH Added' (Site from DM).	MaKayla Bishop (b) (4)	01 Mar 2021 14:08:35
User opened query 'Per DM CLR: Narrative = THERAPEUTIC MANAGEMENT IN ACCORDANCE WITH THE PES GUIDELINES FOR PSYCHOSIS. However, this is not recorded in the ConProc or ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:24:50
User opened query 'Per DM CLR: Narrative = PT HAS HX 2 ADMISSIONS, ONE AT BRV IN FEB 2020 FOR SI AND ONE HERE IN 2013. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:24:41
User opened query 'Per DM CLR: Narrative = PT HAS APPROX 4 SUICIDE ATTEMPTS IN HIS HISTORY, INCLUDING (b) (6). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:24:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1861 of 2247

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PARANOIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:24:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:14:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Amp hetamine, 500 ng/mL Cutoff Negative Negative  Barbiturates UR, 300 ng/mL Cutoff Negative Negative  Buprenorphine, 5 ng/mL Cutoff Negative Negative  Benzodiazepines UR, 300 ng/mL Cutoff Negative Negative  Cocaine UR, 300 ng/mL Cutoff Negative Negative  Methadone, UR, 300 ng/mL Cutoff Negative Negative  Opiates UR, 300 ng/mL Cutoff Negative Negative  Oxycodone, 100 ng/mL Cutoff Negative	MaKayla Bishop (b) (4) (b) (4)	03 Dec 2020 18:31:36

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
gative Negative   Tricyclic Antidepressants, 300 ng/mL Cutoff Negative Negative   Sodium 143 133 - 146 mmol/L   Potassium 4.6 3.5 - 5.3 mmol/L   Chloride 112High 98 - 110 mmol/L   CO2 22 21 - 33 mmol/L <br > Anion Gap 9 3 - 16 mmol/L   BUN 18 7 - 25 mg/dL   Creatinine 2.45High 0.60 - 1.30 mg/dL   Glucose 73 70 - 100 mg/dL   Calcium 9.4 8.6 - 10.3 mg/dL   Osmolality, Calculated 296 278 - 305 mOsm/kg   eGFR AA CKD-EPI 32 See note.   Total Bilirubin 0.7 0.0 - 1.5 mg/dL   Bilirubin, Direct 0.16 0.00 - 0.40 mg/dL   AST 19 13 - 39 U/L <br > ALT 21 7 - 52 U/L   Alkaline Phosphatase 63 36 - 125 U/L   Total Protein 7.9 6.4 - 8.9 g/dL   Albumin 4.3 3.5 - 5.7 g/dL   Bilirubin, Indirect 0.54 0.00 - 1.10 mg/dL   WBC 6.6 3.8 - 10.8 10E3/uL   RBC 4.81 4.20 - 5.80 10E6/uL   Hemoglobin 13.5 13.2 - 17.1 g/dL   Hematocrit 40.6 38.5 - 50.0 %   MCV 84.4 80.0 - 100.0 fL   MCH 28.0 27.0 - 33.0 pg   MCHC 33.1 32.0 - 36.0 g/dL   RDW 14.0 11.0 - 15.0 %   Platelets 205 140 - 400 10E3/uL   MPV 9.1 7.5 - 11.5 fL <br > Neutrophils Relative 63.3 40.0 - 80.0 %   Lymphocytes Relative 15.3 15.0 - 45.0 %   Monocytes Relative 7.1 0.0 - 12.0 %   Eosinophils Relative 12.9High 0.0 - 8.0 %   Basophils Relative 1.4High 0.0 - 1.0 %   nRBC 0 0 - 0 /100 WBC <br > Neutrophils Absolute 4,178 1,500 - 7,800 /uL   Lymphocytes Absolute 1,010 850 - 3,900 /uL   Monocytes Absolute 469 200 - 950 /uL   Eosinophils Absolute 851High 15 - 500 /uL   Basophils Absolute 92 0 - 200 /uL    <br > ' (Site from Safety).		

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1863 of 2247



US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 13:21:54
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no meds or treatment given. pt admitted for observation ' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:54:05
Query 'Please replace Yesterday with actual date: PRESENTED TO PES LOBBY WITH CASE MANAGER YESTERDAY - 26 Oct 2020' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:15:00
User opened query 'Please replace Yesterday with actual date: PRESENTED TO PES LOBBY WITH CASE MANAGER YESTERDAY - 26 Oct 2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:11:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'History of Present Illness: 61 year old male with a History of BAD, schizophrenia who presented to PES lobby with case manger yesterday after being at store and talking to the case manager about obtaining a firearm to shoot people Psychiatric History: HX BAD, Schizophrenia, paranoia. Pt long time outpt follow up with central clinic CM. Pt has approx 4 suicide attempts in his history, including (b) (6). Last attempt 2007. Pt has hx 2 admissions, one at BRV in Feb 2020 for SI and one here in 2013. Pt says that he has a remote history of violence, last spending time in JC in late 90's for assault  He has undergone comprehensive psychiatric evaluation and therapeutic management in accordance with the PES guidelines for psychosis nos. Based on his clinical response and information obtained during this period of observation, it has been determined that he will be admitted to the hospital for ongoing management'	michelle saemann (b) (4)	(b) (4) 03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 14:57:16

**US3662181**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 14:57:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:20:38**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:49:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:57

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: LUMATEPERONE TOSYLATE, PRODUCTSYNONYM: CAPLYTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:10:49
Data point term sent to Coder	System	27 Oct 2020 16:09:44
User entered 'CAPLYTA'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered '42'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered '15 Sep 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:15
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:09:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:09:38



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:11:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:11:35
Data point term sent to Coder	System	27 Oct 2020 16:10:45
User entered 'ESCITALOPRAM'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:46
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:52
User entered 'DEPRESSION'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:53
User entered '10'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:58
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:59
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:19:01
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:10:18
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:03
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:07
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:09
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:19:10
User entered '15 Sep 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:10:18
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:19:12
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:10:18
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:14
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:19:19
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:10:18



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:10:18

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:17:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:12:38
	(b) (4)	
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 16:12:38
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 16:11:45
User entered 'HYDROXYZINE'	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:17:20
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:17:22
User entered 'ANXIETY'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:17:27
User entered '50'	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:03
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:05
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:07
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:13
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:14
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:18
User entered '15 Sep 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:18:20
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:36
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:38
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:18:40
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Dec 2020 15:30:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 15:30:41
Data point term sent to Coder	System	23 Dec 2020 14:02:55
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 14:02:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:12:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:12:38
Data point term sent to Coder	System	27 Oct 2020 16:11:46
User entered 'ASPIRIN'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per CDM: Per CCG V3.0, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 04:16:42
Query 'Per CDM: Per CCG V3.0, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' answered with 'DONE ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	29 Dec 2020 18:45:13
User entered 'Yes (Y)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	29 Dec 2020 18:45:08
User opened query 'Per CDM: Per CCG V3.0, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 07:55:35
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per DM CLR: Please review indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 05:40:51
Query 'Per DM CLR: Please review indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' answered with 'done ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 14:02:13
User entered 'heart health Preventive measure' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 14:02:08
User opened query 'Per DM CLR: Please review indication and provide the medical condition that this medication was used to prevent/treat, rather than the action of the medication. Please update indication as appropriate and ensure to update MH/Adverse event eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 18:06:18
User entered 'BLOOD THINNER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '81'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2018'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 16:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:13:38
Data point term sent to Coder	System	27 Oct 2020 16:12:47
User entered 'ATORVASTATIN'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'HYPERLIPIDEMIA'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '40'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per DM CLR: Please review the start date of this medication as it was recorded as prior to the start date of the corresponding MH record. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 09:15:42
Query 'Per DM CLR: Please review the start date of this medication as it was recorded as prior to the start date of the corresponding MH record. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'medical history entry error in imedidata. should be 7.15.15.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 13:57:23
User entered '15 Jul 2015' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 13:57:00
User opened query 'Per DM CLR: Please review the start date of this medication as it was recorded as prior to the start date of the corresponding MH record. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 18:07:29
User entered '15 Jul 2018'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:11:51
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:51

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:51

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:11:51



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 16:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:13:39
Data point term sent to Coder	System	27 Oct 2020 16:12:46
User entered 'GARLIC'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:06
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '1000'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2015'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:12:20



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:12:20

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 16:15:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:15:43
Data point term sent to Coder	System	27 Oct 2020 16:14:51
User entered 'VITAMIN B COMPLEX'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:24
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '100'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2015'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:14:29

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:14:29

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 16:16:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:16:36
Data point term sent to Coder	System	27 Oct 2020 16:15:55
User entered 'AMLODIPINE BESYLATE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'HYPERTENSION'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '5'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2014'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:15:32
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:15:32

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:15:32

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 16:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:17:38
Data point term sent to Coder	System	27 Oct 2020 16:16:56
User entered 'VITAMIN E'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:46
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '268'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2014'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:16:07

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:16:07

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:16:07



US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:15:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: ASENAPINE MALEATE, PRODUCTSYNONYM: SAPHRIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:19:42
	(b) (4)	
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 16:19:42
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 16:19:01
User entered 'SAPHRIS'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:15:49
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:15:48
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:15:52
User entered '10'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:09
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:10
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:16:12
User entered 'twice daily (BID)'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:13
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:19
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:24
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:16:26
User entered '15 Jul 2013'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:16:36
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:38
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:39
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:16:44
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:18:16



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:18:16

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 17:25:21
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 Oct 2020 17:25:21
Data point term sent to Coder	System	27 Oct 2020 16:22:05
User entered 'TIMOLOL MALEATE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'GLAUCOMA'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '1'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Other (OTHER)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'gtts'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'twice daily (BID)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Other (OTHER)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'OU'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2010'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:21:30
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:21:30

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:21:30

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Feb 2021 11:51:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 11:51:46
Data point term sent to Coder	System	01 Feb 2021 12:38:02
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	01 Feb 2021 12:37:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:45:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:45:20
Data point term sent to Coder	System	05 Nov 2020 14:23:48
User entered 'SODIUM BICARBONATE'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per DM CLR: Please note, there is a medical condition if UNSPECIFIED ACUTE RENAL FAILURE. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. '(Site from DM). Query 'Per DM CLR: Please note, there is a medical condition if UNSPECIFIED ACUTE RENAL FAILURE. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' answered with 'Data updated' (Site from DM). User entered 'UNSPECIFIED ACUTE RENAL FAILURE' reason for change: Data Entry Error User opened query 'Per DM CLR: Please note, there is a medical condition if UNSPECIFIED ACUTE RENAL FAILURE. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. '(Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' canceled (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM). User entered 'CHRONIC RENAL DISEASE'	(b) (4) (b) (4), (b) (6)  Angela Snyder (b) (4) (b) (4)  Angela Snyder (b) (4) (b) (4) (b) (4), (b) (6)  Angela Snyder (b) (4) (b) (4) (b) (4), (b) (6)  (b) (4), (b) (6)  (b) (4), (b) (6)  Brenda Miller (b) (4) (b) (4)	02 Feb 2021 13:13:33  01 Feb 2021 12:37:35  01 Feb 2021 12:37:28 01 Feb 2021 09:37:13  01 Feb 2021 09:36:37  01 Feb 2021 09:28:18  05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User closed query 'Per medication list in subject source dated 26Oct2020 dose is 650 mg BID. Please verify and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:36:18
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 07:29:30
Query 'Per medication list in subject source dated 26Oct2020 dose is 650 mg BID. Please verify and update if needed.' answered with 'done' (Site from CRA).	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 14:00:02
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'done' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 13:59:32
User entered '650' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Dec 2020 13:59:23
User opened query 'Per medication list in subject source dated 26Oct2020 dose is 650 mg BID. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 20:59:41
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 18:08:21
User entered '250'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'twice daily (BID)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '15 Jul 2015'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	05 Nov 2020 14:23:27
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 14:23:27

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 14:23:27

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:01:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:01:02
Data point term sent to Coder	System	01 Mar 2021 15:06:44
Coding entries removed.	Angela Snyder (b) (4)	01 Mar 2021 15:06:02
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BIPOLAR DISORDER should be recorded, update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 09:09:16
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BIPOLAR DISORDER should be recorded, update Con Med indication or provide clarification. ' answered with 'AE is not worsening. Change in med per pt MD ' (Site from DM).	MaKayla Bishop (b) (4)	23 Dec 2020 14:08:27
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BIPOLAR DISORDER should be recorded, update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 18:09:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 17:12:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Nov 2020 17:12:32
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Nov 2020 17:11:34
User entered 'RISPERIDONE'	Brenda Miller (b) (4)	08 Nov 2020 17:10:39
	(b) (4)	



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Un-verified.	Angela Snyder (b) (4)	01 Mar 2021 15:06:02
User entered 'schizoaffective disorder, worsening' reason for change: Data Entry Error	Angela Snyder (b) (4)	01 Mar 2021 15:06:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:10
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:13
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:17
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:25
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:27
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:29
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:04:20
User closed query 'Please verify start dates. Medical records indicate subject administered medication 28-29Oct20. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 02:19:09
Query 'Please verify start dates. Medical records indicate subject administered medication 28-29Oct20. ' answered with 'Med log updated' (Site from CRA).	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:30:10
User opened query 'Please verify start dates. Medical records indicate subject administered medication 28-29Oct20. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:25:50
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:25:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:30
User entered '04 Nov 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:32
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:04:59
DataPoint Un-verified.	Angela Snyder (b) (4)	03 Dec 2020 17:33:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	03 Dec 2020 17:33:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:34
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:05:01
DataPoint Un-verified.	Angela Snyder (b) (4)	03 Dec 2020 17:33:27
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	03 Dec 2020 17:33:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:36
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 17:10:39
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:09:38
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User entered '1'	System	08 Nov 2020 17:10:39

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User entered '1'	System	08 Nov 2020 17:10:39



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:09
User entered '804 (804)'	System	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:28:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:28:22
Data point term sent to Coder	System	18 Dec 2020 18:26:58
User closed query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	System	18 Dec 2020 18:26:49
Query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' answered with 'Data updated' (Site from System).	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:26:49
User entered 'LAMICTAL' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:26:16
User opened query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:28:51
Data point term sent to Coder	System	03 Dec 2020 17:37:03
User entered 'LAMOTRIGINE;TOPAMAX;LAMICTAL'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'BIPOLAR DISORDER'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered '25'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered empty.	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'twice daily (BID)'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered empty.	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered empty.	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered '30 Nov 2020'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered '0'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	18 Dec 2020 18:26:32
User entered 'Yes (Y)'	Angela Snyder (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered '14 Dec 2020' reason for change: Data Entry Error	Angela Snyder (b) (4)	18 Dec 2020 18:26:32
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:26:39
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	03 Dec 2020 17:36:38



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User entered '2'	System	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User entered '1'	System	03 Dec 2020 17:36:38

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:14
User entered '804 (804)'	System	03 Dec 2020 17:36:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:27:00
User closed query 'Per DM CLR: This Con Med had dose increased on 15-DEC-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:15:00
Query 'Per DM CLR: This Con Med had dose increased on 15-DEC-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'not worsening but sx not improving, dose adjustment done, per pt. ' (Site from DM).	michelle saemann (b) (4)	01 Feb 2021 17:49:08
User opened query 'Per DM CLR: This Con Med had dose increased on 15-DEC-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:25:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:35:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:35:50
Data point term sent to Coder	System	18 Dec 2020 18:34:01
User entered 'LAMICTAL'	Angela Snyder (b) (4)	18 Dec 2020 18:33:08
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'BI POLAR DISORDER'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered '100'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered empty.	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'once daily (QD)'	Angela Snyder (b) (4)	18 Dec 2020 18:33:08
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered empty.	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	18 Dec 2020 18:33:08
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered empty.	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered '15 Dec 2020'	Angela Snyder (b) (4)	18 Dec 2020 18:33:08
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered '0'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered empty.	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:27:00
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 18:33:08

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 18:33:08

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 08:01:03
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 Mar 2021 08:01:03
Data point term sent to Coder	System	01 Mar 2021 15:07:45
Data point term sent to Coder	System	23 Feb 2021 15:38:49
User entered 'risperidone'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'schizoaffective disorder, worsening' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	01 Mar 2021 15:07:12
User entered 'bi polar disorder'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'l'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered empty.	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered empty.	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered empty.	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered '28 Oct 2020'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered '30 Oct 2020'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:07:54
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User entered '1'	System	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User entered '1'	System	23 Feb 2021 15:38:10

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:18:17
User entered '804 (804)'	System	23 Feb 2021 15:38:10

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 08:00:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:00:59
Data point term sent to Coder	System	09 Apr 2021 18:08:51
User entered 'klonopin'	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 18:07:53



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'anxiety, no grade change. added to current regimen for anxiety'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '0.5'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	09 Apr 2021 18:07:53



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '3 Apr 2021'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:07:58
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	09 Apr 2021 18:07:53
	(b) (4)	

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:07:53

**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:07:53



**US3662181**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:20:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:07:53

**US3662181**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:20:38**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:22:06
	(b) (4)	

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered		
'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 16:03:38
Un-reviewed for Safety.	System	26 Jan 2021 17:34:46
DataPoint Un-verified.	System	26 Jan 2021 17:34:46
User entered empty.	System	26 Jan 2021 17:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Feb 2021 16:04:03
User entered '2'	System	26 Jan 2021 17:34:46
User entered '1'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered		
'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 16:03:38
Un-reviewed for Safety.	System	26 Jan 2021 17:34:46
DataPoint Un-verified.	System	26 Jan 2021 17:34:46
User entered empty.	System	26 Jan 2021 17:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Feb 2021 16:04:03
User entered '2'	System	26 Jan 2021 17:34:46
User entered '1'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:20:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '04/Nov/2020 15:08'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:20:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered		
'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 16:03:38
Un-reviewed for Safety.	System	26 Jan 2021 17:34:46
DataPoint Un-verified.	System	26 Jan 2021 17:34:46
User entered empty.	System	26 Jan 2021 17:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Feb 2021 16:04:03
User entered '2'	System	26 Jan 2021 17:34:46
User entered '1'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:20:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:12:20
User entered '26/Jan/2021 17:34'	System	26 Jan 2021 17:34:46

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:20:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 16:03:38
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 17:34:46

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered		
'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33



**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 16:03:38
Un-reviewed for Safety.	System	26 Jan 2021 17:34:46
DataPoint Un-verified.	System	26 Jan 2021 17:34:46
User entered empty.	System	26 Jan 2021 17:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:20:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Feb 2021 16:04:03
User entered '2'	System	26 Jan 2021 17:34:46
User entered '1'	System	04 Nov 2020 15:08:04

**US3662181**

**Folder: SAE USA-US088-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:20:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:12:20
User entered '02/Feb/2021 11:04'	System	02 Feb 2021 16:04:03

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:20:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:23:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:12:20
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 16:04:03