

US3462111 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:44

All time stamps listed in this document are displayed in GMT

US3462111

**Form: Participant Creation**

**Data signed:** (b) (4) 19 Feb 2021 19:45:00

**Generated On: 09 Jun 2021 17:40:44**

---

[Participant ID](#)

US3462111

---

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

---

---

US3462111

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

---

US3462111

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Date of Informed Consent (*dd MMM yyyy*) 11 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version  
Amendment 1   
Amendment 2   
Amendment 3   
Amendment 4   
Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail  
Withdrew Consent   
Inclusion/Exclusion   
Cohort Full   
Other

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

Was this participant screened previously? Yes   
No

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

Enrollment Trigger 1

US3462111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Did the participant meet all eligibility criteria?

Yes

No

---

US3462111

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Were any significant conditions reported?

Yes

No

---

US3462111

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Condition	ASTHMA
Start date (dd MMM yyyy)	UN (b) (6) 1962
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)	(b) (6) 1962
Start Year (derived)	1962
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462111

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462111

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Condition	RIGHT FRACTURED RIBS
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3462111

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Condition	CYST REMOVAL (BACK) BENIGN
Start date (dd MMM yyyy)	28 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	28 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3462111

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Condition	OCCASIONAL INSOMNIA
Start date (dd MMM yyyy)	UN APR 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)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462111

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:07 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:07
Height ( <i>xxx.x</i> )	156.0 cm
Weight ( <i>xxx.x</i> )	60.9 kg
BMI ( <i>xxx.x</i> )	25.02465 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3462111

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

11 AUG 2020

---

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

---

US3462111

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*) 11 AUG 2020

Is the participant of childbearing potential? Yes   
No

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN FEB 2017

Date of last menstruation unknown False

US3462111

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

---

**Specify**

---

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

**No Risk Identified** True

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

US3462111

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3462111

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 11 AUG 2020

---

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

---

Folder OID VISIT1

---

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 143571

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

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Height	ND - Not Done
Weight	ND - Not Done

---

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:07 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:07
Temperature ( <i>xxx.x</i> )	99.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	93 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:27 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:27
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	90 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 09:54 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 09:54

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

US3462111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	11 AUG 2020
Collection time ( <i>00:00-23:59</i> )	09:30 (24 HR)
Collection date and time (derived)	11 AUG 2020 09:30

---

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Collection date ( <i>dd MMM yyyy</i> )			11 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	11 AUG 2020 09:32
Nasopharyngeal Swab 2	No		

---

US3462111

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

PC Time Stamp	11 AUG 2020 10:31
PC Open Date & Time	11 AUG 2020 10:14
PC Close Date & Time	11 AUG 2020 12:44

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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 97.3 °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 11 AUG 2020 17:17  
PC Open Date & Time 11 AUG 2020 13:39  
PC Close Date & Time 12 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 17:48
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 18:54
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 16:42
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 16:39
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

PC Time Stamp 16 AUG 2020 16:16

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 AUG 2020 16:50
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**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

11 AUG 2020 10:32

PC Open Date & Time

11 AUG 2020 10:14

PC Close Date & Time

11 AUG 2020 12:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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	11 AUG 2020 17:18
PC Open Date & Time	11 AUG 2020 13:39
PC Close Date & Time	12 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 AUG 2020 17:49
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 18:54

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

14 AUG 2020 16:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 5

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

15 AUG 2020 16:39

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 6

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

16 AUG 2020 16:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

17 AUG 2020 16:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

No

Yes

PC Time stamp	11 AUG 2020 10:33
PC Open Date & Time	11 AUG 2020 10:14
PC Close Date & Time	11 AUG 2020 12:44

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

No   
Yes

---

PC Time stamp	11 AUG 2020 17:19
PC Open Date & Time	11 AUG 2020 13:39
PC Close Date & Time	12 AUG 2020 11:59

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 17:50
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 18:55
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 16:43
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 16:40
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

---

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

---

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

---

Yes

---

PC Time stamp	17 AUG 2020 16:51
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

---

US3462111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:38

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:38

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

*If Contact Not Made, please provide Comments*

US3462111

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:38

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 15 SEP 2020

---

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

---

Folder OID VISIT2

---

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:58 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:58
Temperature ( <i>xxx.x</i> )	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	96 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:20 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 13:20
Temperature ( <i>xxx.x</i> )	99.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 12:42

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

US3462111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 15 SEP 2020

---

Collection time (*00:00-23:59*) 12:30 (24 HR)

---

Collection date and time (derived) 15 SEP 2020 12:30

---

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Collection date ( <i>dd MMM yyyy</i> )			15 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:32	15 SEP 2020 12:32
Nasopharyngeal Swab 2	No		

---

US3462111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**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 99.1 °F

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

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

PC Time Stamp 15 SEP 2020 13:24

PC Open Date & Time 15 SEP 2020 13:02

PC Close Date & Time 15 SEP 2020 15:32

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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 97.8 °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 15 SEP 2020 17:36  
PC Open Date & Time 15 SEP 2020 16:27  
PC Close Date & Time 16 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 17:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 17:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 SEP 2020 16:37
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 18:35
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 17:48
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 04:08
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**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	15 SEP 2020 13:25
PC Open Date & Time	15 SEP 2020 13:02
PC Close Date & Time	15 SEP 2020 15:32

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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

15 SEP 2020 17:37

PC Open Date & Time

15 SEP 2020 16:27

PC Close Date & Time

16 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 2

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

16 SEP 2020 17:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 17:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 4

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

18 SEP 2020 16:38

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 5

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 SEP 2020 18:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 6

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

20 SEP 2020 17:48

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 7

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 SEP 2020 04:08

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

No   
Yes

---

PC Time stamp	15 SEP 2020 13:25
PC Open Date & Time	15 SEP 2020 13:02
PC Close Date & Time	15 SEP 2020 15:32

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

No

Yes

---

PC Time stamp	15 SEP 2020 17:37
PC Open Date & Time	15 SEP 2020 16:27
PC Close Date & Time	16 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 17:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 17:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 16:38
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 18:36
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 17:49
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

---

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**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

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

---

	Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 04:08
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

---

US3462111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 13 OCT 2020

---

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

---

Folder OID VISIT3

---

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 13 OCT 2020

---

Collection time (*00:00-23:59*) 09:00 (24 HR)

---

Collection date and time (derived) 13 OCT 2020 09:00

---

US3462111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:24:41

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 99

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

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

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2020 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 110

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2020 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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 11 DEC 2020 07:10:08

Patient Cloud Open Date & Time 10 DEC 2020 00:01

Patient Cloud Close Date & Time 14 DEC 2020 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 08:02:42
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 17:21:37
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 10:43:37
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 07 JAN 2021 06:35:50

Patient Cloud Open Date & Time 07 JAN 2021 00:01

Patient Cloud Close Date & Time 11 JAN 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 15 JAN 2021 12:49:52

Patient Cloud Open Date & Time 14 JAN 2021 00:01

Patient Cloud Close Date & Time 18 JAN 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

---

**TIMEPOINT**

DAY 166

---

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

No

Yes

---

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

No

Yes

---

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

---

Date and time of submission

21 JAN 2021 08:52:17

---

Patient Cloud Open Date & Time

21 JAN 2021 00:01

---

Patient Cloud Close Date & Time

25 JAN 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 07:31:07
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission 04 FEB 2021 19:41:31

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 06:39:25
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission

18 FEB 2021 06:43:36

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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 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	25 FEB 2021 14:48:42
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 215

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 222

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 229

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 MAR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 236

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 MAY 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 292

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#) 21 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#) 25 OCT 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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   
Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 481

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 530

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 FEB 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

31 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 APR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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   
Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

[Patient Cloud Close Date & Time](#) 11 APR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 614

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 642

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 712

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 719

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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  Yes

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 AUG 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 754

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**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°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 789

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

---

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#) 13 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#) 17 OCT 2022 23:59

---

**US3462111**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 17:40:44**

---

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
---	--	---------------------------

---

---

US3462111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:45:02

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:45:02

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:45:02

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:45:02

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) \_\_\_\_\_

---

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

---

Comments \_\_\_\_\_

---

*If Contact Not Made, please provide Comments* \_\_\_\_\_

---

US3462111

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (dd MMM yyyy) \_\_\_\_\_

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

Comments

*If Contact Not Made, please provide Comments* \_\_\_\_\_

US3462111

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 17 MAR 2021

---

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

---

Folder OID VISIT4

---

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:05:06

Generated On: 09 Jun 2021 17:40:44

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 17 MAR 2021

---

Collection time (*00:00-23:59*) 09:02 (24 HR)

---

Collection date and time (derived) 17 MAR 2021 09:02

---

US3462111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) \_\_\_\_\_

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

Comments \_\_\_\_\_

*If Contact Not Made, please provide Comments* \_\_\_\_\_

US3462111

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3462111

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:44

---

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"/>

---

US3462111

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:44

---

Generate Next COVID-19 Assessment

Yes

No

---

US3462111

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:45:01

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 15 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3462111

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

Form: Unblinding

Data signed: (b) (4) 19 Apr 2021 21:10:35

Generated On: 09 Jun 2021 17:40:44

Date of updated informed consent ( <i>dd MMM yyyy</i> )	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3462111

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 22:32:57

Generated On: 09 Jun 2021 17:40:44

---

Height	156 cm
Weight	62.6 kg
BMI (xxx.x)	25.72321

---

US3462111

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 22:32:57

Generated On: 09 Jun 2021 17:40:44

Height	156 cm
Weight	62.6 kg
BMI (xxx.x)	25.72321
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)	15 JAN 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 09:40
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	TYMPANIC
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 22:32:57

Generated On: 09 Jun 2021 17:40:44

Height	156 cm
Weight	62.6 kg
BMI (xxx.x)	25.72321
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)	15 JAN 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 11:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:45:01

Generated On: 09 Jun 2021 17:40:44

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

15 JAN 2021

---

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

---

US3462111

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

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) 15 JAN 2021

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 10:33

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

What was the frequency of the study treatment dosing? ONCE

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

US3462111

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 15 JAN 2021

---

Collection time (*00:00-23:59*) 09:35 (24 HR)

---

Collection date and time (derived) 15 JAN 2021 09:35

---

US3462111

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 15 JAN 2021

---

Collection time (*00:00 - 23:59*) 09:26

---

Collection Date and Time (derived) 15 JAN 2021 09:26

---

US3462111

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462111

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

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

---

US3462111

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	10 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	13:58 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 13:58
Temperature ( <i>xxx.x</i> )	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 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> )	86 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

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 ( <i>dd MMM yyyy</i> )	10 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	15:49 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 15:49
Temperature ( <i>xxx.x</i> )	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG

US3462111

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 15:18 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 15:18

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

US3462111

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) \_\_\_\_\_

---

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

---

Comments \_\_\_\_\_

---

*If Contact Not Made, please provide Comments* \_\_\_\_\_

---

US3462111

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462111

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 17 MAR 2021

---

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

---

Folder OID OLD57

---

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) \_\_\_\_\_

Time of assessment (*00:00-23:59*) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (*xxx.x*) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (*xxx*) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (*xxx*) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (*xxx*) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (*xxx*) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462111

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

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.*

---

US3462111

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:11:44

Generated On: 09 Jun 2021 17:40:44

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 17 MAR 2021

---

Collection time (*00:00-23:59*) 09:02 (24 HR)

---

Collection date and time (derived) 17 MAR 2021 09:02

---

US3462111

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

AEID USA-US093-2020-MRNA-1273-P30  
1000004

Adverse event LARYNGEAL EDEMA

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 19 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 24 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 19 SEP 2020

Hospital Discharge Date (dd MMM yyyy) 20 SEP 2020

Admitted to ICU? Yes   
No   
Unknown

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

57 YEAR OLD WOMAN WITH  
ASTHMA AND PMH OF  
HYPERTENSION CONSENTED  
AND RANDOMIZED FOR  
MODERNA ON 11AUG2020 AND  
RECEIVED VISIT 2 DOSE ON  
15SEP2020. PATIENT HAD  
ACUTE LARYNGEAL EDEMA  
EPISODE WHILE DOING  
OUTDOOR YARDWORK ON  
08:00 ON 19SEP2020. SHE WAS  
ADMITTED TO LOCAL  
HOSPITAL ICU, AND  
TREATMENT WITH  
DISCONTINUATION OF  
CON-MED LISINAPRIL 5 MG  
DAILY, AS WELL WITH  
SYSTEMIC STEROIDS AND HER  
REGULAR ASTHMA  
MEDICATIONS. THE  
LARYNGEAL EDEMA  
IMPROVED BY 20SEP2020 AND  
PATIENT WAS DISCHARGED TO  
HOME ON 5 DAYS OF  
PREDNISONE COMPLETED ON  
24SEP2020 BY 12:00. SHE IS NOW  
USING AN ALTERNATE BLOOD  
PRESSURE MEDICATION  
OLMESARTAN5 MG DAILY. THE  
PHYSICIANS TREATING  
PATIENT ATTRIBUTED  
LARYNGEAL EDEMA EPISODE  
TO HER CON-MED LISINAPRIL  
5MG DAILY, AND  
DISCONTINUED THIS

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

MEDICATION ON 20SEP2020.  
LISINOPRIL HAD BEEN USED  
SINCE SEPTEMBER 2018. THE  
SAE WAS FELT NOT-RELATED  
TO THE STUDY VACCINE. ALL  
HISTORY FROM PATIENT  
PHONE CALL AT 15:00 ON  
23SEP2020. SAE IS REPORTED  
ON ECRF TODAY.

---

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)	1

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

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

Yes

No

---

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

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication ADVAIR 250/50

Prophylaxis Yes   
No

Indication ASTHMA

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 27 NOV 2018

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication ALBUTEROL

Prophylaxis Yes   
No

Indication ASTHMA

Dose per administration 180

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 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 1982

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication LISINOPRIL

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)

372 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN SEP 2018

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 19 SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication VITAMIN D3

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 5000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) UN UNK 2011

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication VITAMIN B12

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)

376 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2011

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication MAGNESIUM

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 400

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2011

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication BIOTIN

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2011

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication OCCASIONAL HEADACHES

Dose per administration 200

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) \_\_\_\_\_ UN UNK 2012

---

Start date completely unknown \_\_\_\_\_ False

---

Ongoing? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) \_\_\_\_\_ 802

\_\_\_\_\_ 803

\_\_\_\_\_ 804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication BLACK COHASH

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

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*) 11 APR 2019

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication TYLENOL PM

Prophylaxis Yes   
No

Indication OCCASIONAL INSOMNIA

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) \_\_\_\_\_ UN APR 2020

---

Start date completely unknown \_\_\_\_\_ False

---

Ongoing? Yes  No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes  No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication OLMESARTAN

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)

388 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

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) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

Name of Medication PREDNISONE

Prophylaxis Yes   
No

Indication LARYNGEAL EDEMA

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2209

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 19:45:00

Generated On: 09 Jun 2021 17:40:44

---

	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 ( <i>dd MMM yyyy</i> )	19 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date ( <i>dd MMM yyyy</i> )	24 SEP 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"/>

---

US3462111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:44

---

Were any concomitant procedures performed?

Yes

No

---

**If yes, please complete Concomitant Procedures form.**

---

US3462111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:44

---

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

---

US3462111

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:44

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

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:45:01

Generated On: 09 Jun 2021 17:40:44

SAEID	USA-US093-2020-MRNA-1273-P30 1000004
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:45:01

Generated On: 09 Jun 2021 17:40:44

SAEID	USA-US093-2020-MRNA-1273-P301000004
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/SEP/2020 15:54
<b>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.</b>	True

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:45:01

Generated On: 09 Jun 2021 17:40:44

SAEID	USA-US093-2020-MRNA-1273-P301000004
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/NOV/2020 23:37
<b>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.</b>	True

Audit

US3462111 (Prod: Crisor, LLC)

US3462111

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:40:44**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'US3462111'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:54:16

US3462111

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Savannah Peterson (b) (4)	11 Aug 2020 17:10:29

US3462111

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:54:17

US3462111

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Clinic (Clinic)'	Savannah Peterson (b) (4)	11 Aug 2020 17:10:29

US3462111

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'SCRN'	System	11 Aug 2020 17:10:29

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per CDM: Please complete this page, data is required.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete this page, data is required.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 14:30:20
User opened query 'Per CDM: Please complete this page, data is required.' (Site from DM).	Savannah Peterson (b) (4)	03 Sep 2020 21:18:57
User entered (b) (6) 1962'	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 14:28:38
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	11 Aug 2020 15:54:19

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '57'	(b) (4) Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'YEARS'	System	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '57'	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Female (F)'	Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '1'	Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Savannah Peterson (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	03 Sep 2020 21:18:42

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	Savannah Peterson (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Aug 2020'	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2020'	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Amendment 2 (2)'	Savannah Peterson (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Savannah Peterson (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Savannah Peterson (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	Savannah Peterson (b) (4)	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:54:17

US3462111

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'I'	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	11 Aug 2020 17:10:43

US3462111

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 23:59:01

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 23:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 23:59:44
Data point term sent to Coder	System	15 Sep 2020 23:59:35
User entered 'ASTHMA'	(b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	09 Oct 2020 20:23:03
User entered 'UN (b) (6) 1962' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:23:03
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	15 Sep 2020 23:59:22
User entered 'UN UNK 1962'	(b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered (b) (6) 1962'	System	09 Oct 2020 20:23:03
User entered 'Jan 1962'	System	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '1962'	System	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	15 Sep 2020 23:59:22

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 00:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 00:02:50
Data point term sent to Coder	System	16 Sep 2020 00:01:39
User entered 'HYPERTENSION'	(b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2015'	System	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2015'	System	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:00:50

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:02:50
Data point term sent to Coder	System	16 Sep 2020 00:01:39
User entered 'LEFT OVARIAN CYST'	(b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2009'	System	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2009'	System	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2009'	System	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2009'	System	16 Sep 2020 00:01:30

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 13:16:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 13:16:14
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 21:03:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 21:03:45
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 00:03:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 00:03:50
Data point term sent to Coder System	System	16 Sep 2020 00:02:40
User entered 'OCCASIONAL HEADACHES'	(b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 1985'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 1985'	System	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '1985'	System	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:01:46

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fractured ribs - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 05:19:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 05:19:50
Data point term sent to Coder	System	16 Sep 2020 00:02:40
User entered 'RIGHT FRACTURED RIBS'	(b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2011'	System	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2011'	System	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2011'	System	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2011'	System	16 Sep 2020 00:02:23

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:21:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:21:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:05:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:05:53
Data point term sent to Coder	System	16 Sep 2020 00:04:45
User entered 'SULFA ALLERGY (HIVES)'	(b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 1985'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 1985'	System	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '1985'	System	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	16 Sep 2020 00:03:55

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy left - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:05:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 00:05:52
Data point term sent to Coder	System	16 Sep 2020 00:04:44
User entered 'OOPHORECTOMY LEFT'	(b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2009'	System	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2009'	System	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Jan 2009'	System	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2009'	System	16 Sep 2020 00:04:41

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:33:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 21:33:25
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:55:34
Data point term sent to Coder	System	05 Nov 2020 23:49:54
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4)	05 Nov 2020 23:49:44
Coding entries removed.	Savannah Peterson (b) (4)	05 Nov 2020 23:49:29
User entered 'CYST REMOVAL (BACK) benign' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 23:49:29
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:01:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 06:31:56

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	16 Sep 2020 06:31:56 16 Sep 2020 00:06:47
User entered 'CYST REMOVAL (BACK)'	(b) (4), (b) (6) [Redacted] [Redacted]	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '28 Feb 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '28 Feb 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Feb 2020'	System	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2020'	System	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Feb 2020'	System	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2020'	System	16 Sep 2020 00:06:08

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 23:50:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 23:50:24
Data point term sent to Coder	System	05 Nov 2020 23:49:54
User entered 'occasional insomnia'	Savannah Peterson (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'un Apr 2020'	Savannah Peterson (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Apr 2020'	System	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2020'	System	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered empty.	System	05 Nov 2020 23:48:56

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 00:02:24
Data point term sent to Coder	System	06 Nov 2020 00:01:11
User entered 'post menopausal'	Savannah Peterson (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'un Feb 2017'	Savannah Peterson (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	Savannah Peterson (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'un Feb 2017'	Savannah Peterson (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '0'	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Feb 2017'	System	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2017'	System	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'Feb 2017'	System	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '2017'	System	06 Nov 2020 00:01:01

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '09:07'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered '11 Aug 2020 09:07'	System	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '156.0' cm	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12
DataPoint set to visible.	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '60.9' kg	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12
DataPoint set to visible.	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
Amendment Manager: User entered '25.02465'	System	16 Sep 2020 23:51:40
User entered '25.0'	System	13 Aug 2020 17:26:12
DataPoint set to visible.	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'kg/m2'	System	13 Aug 2020 17:26:12
DataPoint set to visible.	System	11 Aug 2020 17:10:59

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 06:06:08
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:53:01
User entered '99.0' F	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User entered '93'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'bpm'	System	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User entered '15'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'breaths/min'	System	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User entered '144'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'mmHg'	System	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:31
User entered '90'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User entered 'mmHg'	System	13 Aug 2020 17:26:12

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26

US3462111

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:20

US3462111

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:27:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 00:07:50
User entered '11 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:20

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:41:43
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:59:38
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 03:33:33
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'UN Feb 2017'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:44

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:06:53

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

**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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

**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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

**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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
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	13 Aug 2020 17:26:40
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:40
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:26:35
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '1'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

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)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:22:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:26:35

US3462111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:29

US3462111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:29

US3462111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:29

US3462111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'VISIT1'	System	13 Aug 2020 17:28:29

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:57

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:34:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:34:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:44:57
User entered '143571' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:57

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:44:57

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

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)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:35

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

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)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:35

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:35

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:35

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:35

US3462111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:16:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:30:47

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 12:18:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:53:20
User entered '156' cm	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered '60.9' kg	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 12:18:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:53:20
User entered '156' cm	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered '60.9' kg	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Pre-Dose (PREDOSE)'	Daniel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '09:07'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '11 Aug 2020 09:07'	System	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '99.0' F	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '93'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'bpm'	System	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'breaths/min'	System	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '144'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '90'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 12:18:21
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:53:20
User entered '156' cm	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered '60.9' kg	Danuel Hamlin (b) (4)	13 Aug 2020 17:27:33

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Post-Dose (POSTDOSE)'	Daniel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 12:10:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 17:28:11
User entered '10:27'	Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '11 Aug 2020 10:27'	System	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '98.7' F	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:17:12
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '90'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'bpm'	System	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '14'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'breaths/min'	System	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '130'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '88'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	13 Aug 2020 17:28:11

US3462111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:41

US3462111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:41

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Savannah Peterson (b) (4)	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

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)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	Savannah Peterson (b) (4)	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	11 Aug 2020 17:11:29
	(b) (4)	

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '09:54'	Savannah Peterson (b) (4) (b) (4)	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '11 Aug 2020 09:54'	System	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4)	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'ONCE'	System	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 17:11:29

US3462111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:53

US3462111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:53

US3462111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '09:30'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:28:53

US3462111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '11 Aug 2020 09:30'	System	13 Aug 2020 17:28:53

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daniel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '09:32'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '11 Aug 2020 09:32'	System	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daniel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Aug 2020 17:29:06

US3462111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 17:29:19

US3462111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	13 Aug 2020 17:29:19

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:30:58', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5138845c-4db5-4eca-a105-6b150bcf4143'	System	11 Aug 2020 17:31:40
User entered 'Yes (Y)'	System	11 Aug 2020 17:31:40

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:31:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5138845c-4db5-4eca-a105-6b150bcf4143'	System	11 Aug 2020 17:31:40
User entered '98.7'	System	11 Aug 2020 17:31:40

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:31:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5138845c-4db5-4eca-a105-6b150bcf4143'	System	11 Aug 2020 17:31:40
User entered 'No (N)'	System	11 Aug 2020 17:31:40

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:31:37', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5138845c-4db5-4eca-a105-6b150bcf4143'	System	11 Aug 2020 17:31:40
User entered '11 Aug 2020 10:31'	System	11 Aug 2020 17:31:40

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 10:14'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 12:44'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:16:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95eafe04-7f21-424b-8772-e367e1dd67fc'	System	12 Aug 2020 00:17:13
User entered 'Yes (Y)'	System	12 Aug 2020 00:17:13

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:16:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95eafe04-7f21-424b-8772-e367e1dd67fc'	System	12 Aug 2020 00:17:13
User entered '97.3'	System	12 Aug 2020 00:17:13

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:17:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95eafe04-7f21-424b-8772-e367e1dd67fc'	System	12 Aug 2020 00:17:13
User entered 'No (N)'	System	12 Aug 2020 00:17:13

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:17:10', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95eafe04-7f21-424b-8772-e367e1dd67fc'	System	12 Aug 2020 00:17:13
User entered '11 Aug 2020 17:17'	System	12 Aug 2020 00:17:13

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 13:39'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 2'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:46:33', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '304506c3-afc4-4c0f-8d76-f15ab6d60716'	System	13 Aug 2020 00:48:30
User entered 'Yes (Y)'	System	13 Aug 2020 00:48:30

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:48:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '304506c3-afc4-4c0f-8d76-f15ab6d60716'	System	13 Aug 2020 00:48:30
User entered '98.6'	System	13 Aug 2020 00:48:30

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:48:14', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '304506c3-afc4-4c0f-8d76-f15ab6d60716'	System	13 Aug 2020 00:48:30
User entered 'No (N)'	System	13 Aug 2020 00:48:30

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:48:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '304506c3-afc4-4c0f-8d76-f15ab6d60716'	System	13 Aug 2020 00:48:30
User entered '12 Aug 2020 17:48'	System	13 Aug 2020 00:48:30

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 3'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:53:16', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '13554586-a362-4d77-8e4e-5d819057dd95'	System	14 Aug 2020 01:54:18
User entered 'Yes (Y)'	System	14 Aug 2020 01:54:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:03', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '13554586-a362-4d77-8e4e-5d819057dd95'	System	14 Aug 2020 01:54:18
User entered '98.4'	System	14 Aug 2020 01:54:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:10', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '13554586-a362-4d77-8e4e-5d819057dd95'	System	14 Aug 2020 01:54:18
User entered 'No (N)'	System	14 Aug 2020 01:54:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '13554586-a362-4d77-8e4e-5d819057dd95'	System	14 Aug 2020 01:54:18
User entered '13 Aug 2020 18:54'	System	14 Aug 2020 01:54:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 4'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:41:23', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bdfdd29c-b339-45bb-b032-e7550b413af8'	System	14 Aug 2020 23:43:18
User entered 'Yes (Y)'	System	14 Aug 2020 23:43:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:41:34', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bdfdd29c-b339-45bb-b032-e7550b413af8'	System	14 Aug 2020 23:43:18
User entered '97.5'	System	14 Aug 2020 23:43:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bdfdd29c-b339-45bb-b032-e7550b413af8'	System	14 Aug 2020 23:43:18
User entered 'No (N)'	System	14 Aug 2020 23:43:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:20', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bdfdd29c-b339-45bb-b032-e7550b413af8'	System	14 Aug 2020 23:43:18
User entered '14 Aug 2020 16:42'	System	14 Aug 2020 23:43:18

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 5'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:38:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'cd075d1f-84eb-4c22-890c-2c46615892a2'	System	15 Aug 2020 23:39:25
User entered 'Yes (Y)'	System	15 Aug 2020 23:39:25

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'cd075d1f-84eb-4c22-890c-2c46615892a2'	System	15 Aug 2020 23:39:25
User entered '97.8'	System	15 Aug 2020 23:39:25

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:06', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'cd075d1f-84eb-4c22-890c-2c46615892a2'	System	15 Aug 2020 23:39:25
User entered 'No (N)'	System	15 Aug 2020 23:39:25

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'cd075d1f-84eb-4c22-890c-2c46615892a2'	System	15 Aug 2020 23:39:25
User entered '15 Aug 2020 16:39'	System	15 Aug 2020 23:39:25

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 6'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:15:46', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '907e4aa8-17a3-40ba-be62-04f5627b3784'	System	16 Aug 2020 23:17:24
User entered 'Yes (Y)'	System	16 Aug 2020 23:17:24

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '907e4aa8-17a3-40ba-be62-04f5627b3784' User entered '98.9'	System	16 Aug 2020 23:17:24
	System	16 Aug 2020 23:17:24

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '907e4aa8-17a3-40ba-be62-04f5627b3784'	System	16 Aug 2020 23:17:24
User entered 'No (N)'	System	16 Aug 2020 23:17:24

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '907e4aa8-17a3-40ba-be62-04f5627b3784' User entered '16 Aug 2020 16:16'	System	16 Aug 2020 23:17:24
	System	16 Aug 2020 23:17:24

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 7'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:49:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '445806fb-7b59-4a41-89c9-41323d60aa9f' User entered 'Yes (Y)'	System	17 Aug 2020 23:51:01
	System	17 Aug 2020 23:51:01

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '445806fb-7b59-4a41-89c9-41323d60aa9f' User entered '98.3'	System	17 Aug 2020 23:51:01
	System	17 Aug 2020 23:51:01

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '445806fb-7b59-4a41-89c9-41323d60aa9f'	System	17 Aug 2020 23:51:01
User entered 'No (N)'	System	17 Aug 2020 23:51:01

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '445806fb-7b59-4a41-89c9-41323d60aa9f' User entered '17 Aug 2020 16:50'	System	17 Aug 2020 23:51:01
	System	17 Aug 2020 23:51:01

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e1f28c5f-73ab-4425-bc05-bc767859248e'	System	11 Aug 2020 17:32:54
User entered 'None (1)'	System	11 Aug 2020 17:32:54

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e1f28c5f-73ab-4425-bc05-bc767859248e'	System	11 Aug 2020 17:32:54
User entered 'No (N)'	System	11 Aug 2020 17:32:54

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e1f28c5f-73ab-4425-bc05-bc767859248e'	System	11 Aug 2020 17:32:54
User entered 'No (N)'	System	11 Aug 2020 17:32:54

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e1f28c5f-73ab-4425-bc05-bc767859248e'	System	11 Aug 2020 17:32:54
User entered 'None (1)'	System	11 Aug 2020 17:32:54

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:51', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e1f28c5f-73ab-4425-bc05-bc767859248e' User entered '11 Aug 2020 10:32'	System	11 Aug 2020 17:32:54
	System	11 Aug 2020 17:32:54

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 10:14'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 12:44'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:17:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '44f3e2be-52a5-4ca1-a8b0-a3fff345603b'	System	12 Aug 2020 00:18:18
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 00:18:18

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:17:37', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '44f3e2be-52a5-4ca1-a8b0-a3ff345603b'	System	12 Aug 2020 00:18:18
User entered 'No (N)'	System	12 Aug 2020 00:18:18

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:17:58', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '44f3e2be-52a5-4ca1-a8b0-a3ff345603b'	System	12 Aug 2020 00:18:18
User entered 'No (N)'	System	12 Aug 2020 00:18:18

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:08', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '44f3e2be-52a5-4ca1-a8b0-a3ff345603b' User entered 'None (1)'	System	12 Aug 2020 00:18:18
	System	12 Aug 2020 00:18:18

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:16', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '44f3e2be-52a5-4ca1-a8b0-a3ff345603b'	System	12 Aug 2020 00:18:18
User entered '11 Aug 2020 17:18'	System	12 Aug 2020 00:18:18

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 13:39'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 2'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:48:53', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ebbf1c5-325f-4a5e-bdb8-2bec28616e70'	System	13 Aug 2020 00:49:27
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:49:27

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:48:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ebbfa1c5-325f-4a5e-bdb8-2bec28616e70'	System	13 Aug 2020 00:49:27
User entered 'No (N)'	System	13 Aug 2020 00:49:27

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ebbfa1c5-325f-4a5e-bdb8-2bec28616e70'	System	13 Aug 2020 00:49:27
User entered 'No (N)'	System	13 Aug 2020 00:49:27

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:16', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ebbf1c5-325f-4a5e-bdb8-2bec28616e70'	System	13 Aug 2020 00:49:27
User entered 'None (1)'	System	13 Aug 2020 00:49:27

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ebbf1c5-325f-4a5e-bdb8-2bec28616e70' User entered '12 Aug 2020 17:49'	System	13 Aug 2020 00:49:27
	System	13 Aug 2020 00:49:27

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 3'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ed42f88d-13cd-4eb3-9897-c2607b777e17'	System	14 Aug 2020 01:54:44
User entered 'None (1)'	System	14 Aug 2020 01:54:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:27', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ed42f88d-13cd-4eb3-9897-c2607b777e17'	System	14 Aug 2020 01:54:44
User entered 'No (N)'	System	14 Aug 2020 01:54:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ed42f88d-13cd-4eb3-9897-c2607b777e17'	System	14 Aug 2020 01:54:44
User entered 'No (N)'	System	14 Aug 2020 01:54:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ed42f88d-13cd-4eb3-9897-c2607b777e17'	System	14 Aug 2020 01:54:44
User entered 'None (1)'	System	14 Aug 2020 01:54:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:41', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ed42f88d-13cd-4eb3-9897-c2607b777e17'	System	14 Aug 2020 01:54:44
User entered '13 Aug 2020 18:54'	System	14 Aug 2020 01:54:44

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 4'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b57102e4-6bf1-48bc-aa09-bc0f15160d85'	System	14 Aug 2020 23:43:36
User entered 'None (1)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:28', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b57102e4-6bf1-48bc-aa09-bc0f15160d85'	System	14 Aug 2020 23:43:36
User entered 'No (N)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:30', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b57102e4-6bf1-48bc-aa09-bc0f15160d85'	System	14 Aug 2020 23:43:36
User entered 'No (N)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b57102e4-6bf1-48bc-aa09-bc0f15160d85'	System	14 Aug 2020 23:43:36
User entered 'None (1)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:42:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b57102e4-6bf1-48bc-aa09-bc0f15160d85'	System	14 Aug 2020 23:43:36
User entered '14 Aug 2020 16:42'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 5'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '57478e57-4788-4c31-b5c3-1ccf00e06612'	System	15 Aug 2020 23:39:48
User entered 'None (1)'	System	15 Aug 2020 23:39:48

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:27', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '57478e57-4788-4c31-b5c3-1ccf00e06612'	System	15 Aug 2020 23:39:48
User entered 'No (N)'	System	15 Aug 2020 23:39:48

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '57478e57-4788-4c31-b5c3-1ccf00e06612'	System	15 Aug 2020 23:39:48
User entered 'No (N)'	System	15 Aug 2020 23:39:48

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:38', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '57478e57-4788-4c31-b5c3-1ccf00e06612'	System	15 Aug 2020 23:39:48
User entered 'None (1)'	System	15 Aug 2020 23:39:48

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:42', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '57478e57-4788-4c31-b5c3-1ccf00e06612'	System	15 Aug 2020 23:39:48
User entered '15 Aug 2020 16:39'	System	15 Aug 2020 23:39:48

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 6'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2bb8671f-8025-4e19-93d1-2f2a344917f5'	System	16 Aug 2020 23:17:25
User entered 'None (1)'	System	16 Aug 2020 23:17:25

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2bb8671f-8025-4e19-93d1-2f2a344917f5'	System	16 Aug 2020 23:17:25
User entered 'No (N)'	System	16 Aug 2020 23:17:25

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:34', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2bb8671f-8025-4e19-93d1-2f2a344917f5'	System	16 Aug 2020 23:17:25
User entered 'No (N)'	System	16 Aug 2020 23:17:25

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2bb8671f-8025-4e19-93d1-2f2a344917f5'	System	16 Aug 2020 23:17:25
User entered 'None (1)'	System	16 Aug 2020 23:17:25

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:39', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2bb8671f-8025-4e19-93d1-2f2a344917f5'	System	16 Aug 2020 23:17:25
User entered '16 Aug 2020 16:16'	System	16 Aug 2020 23:17:25

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 7'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:35', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '87f3db0e-81fc-4e2d-9261-59dce30c59f4'	System	17 Aug 2020 23:51:43
User entered 'None (1)'	System	17 Aug 2020 23:51:43

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '87f3db0e-81fc-4e2d-9261-59dce30c59f4'	System	17 Aug 2020 23:51:43
User entered 'No (N)'	System	17 Aug 2020 23:51:43

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:43', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '87f3db0e-81fc-4e2d-9261-59dce30c59f4'	System	17 Aug 2020 23:51:43
User entered 'No (N)'	System	17 Aug 2020 23:51:43

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:48', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '87f3db0e-81fc-4e2d-9261-59dce30c59f4'	System	17 Aug 2020 23:51:43
User entered 'None (1)'	System	17 Aug 2020 23:51:43

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:51', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '87f3db0e-81fc-4e2d-9261-59dce30c59f4'	System	17 Aug 2020 23:51:43
User entered '17 Aug 2020 16:50'	System	17 Aug 2020 23:51:43

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5'	System	11 Aug 2020 17:33:42
User entered 'None (0)'	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:32:59', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5'	System	11 Aug 2020 17:33:42
User entered 'None (0)'	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:02', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5' User entered 'None (0)'	System	11 Aug 2020 17:33:42
	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5'	System	11 Aug 2020 17:33:42
User entered 'None (0)'	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5' User entered 'None (0)'	System	11 Aug 2020 17:33:42
	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:10', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5'	System	11 Aug 2020 17:33:42
User entered 'None (0)'	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:30', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5'	System	11 Aug 2020 17:33:42
User entered 'No (N)'	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T10:33:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5bb0325c-9ab9-411e-aba3-86da1d5d5ee5' User entered '11 Aug 2020 10:33'	System	11 Aug 2020 17:33:42
	System	11 Aug 2020 17:33:42

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 10:14'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 12:44'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'None (0)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:39', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'No interference with activity (1)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:48', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'None (0)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:18:52', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'None (0)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:19:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'None (0)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:19:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'None (0)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:19:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered 'No (N)'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-11T17:19:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6f784cc8-4685-4fd6-b331-8e04acb5e243'	System	12 Aug 2020 00:19:21
User entered '11 Aug 2020 17:19'	System	12 Aug 2020 00:19:21

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '11 Aug 2020 13:39'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 2'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:28', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'None (0)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:54', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd'	System	13 Aug 2020 00:50:19
User entered 'Some interference with activity (2)'	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:49:59', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'None (0)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:50:02', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'None (0)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:50:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'None (0)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:50:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'None (0)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:50:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered 'No (N)'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-12T17:50:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2a6d272b-b46a-443f-98e8-07ab059976cd' User entered '12 Aug 2020 17:50'	System	13 Aug 2020 00:50:19
	System	13 Aug 2020 00:50:19

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 3'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:51', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:54:57', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:08', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'None (0)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:19', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered 'No (N)'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-13T18:55:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e90727b2-1b0c-4bcd-b94e-6af72095f5a9'	System	14 Aug 2020 01:55:30
User entered '13 Aug 2020 18:55'	System	14 Aug 2020 01:55:30

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 4'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:06', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'No interference with activity (1)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'None (0)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:14', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'None (0)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:16', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'None (0)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:19', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'None (0)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'None (0)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered 'No (N)'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-14T16:43:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a5c3255c-9508-424c-96ff-8e762bbd6565'	System	14 Aug 2020 23:43:36
User entered '14 Aug 2020 16:43'	System	14 Aug 2020 23:43:36

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 5'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:46', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:49', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:52', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:53', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:55', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:39:57', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'None (0)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:40:02', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered 'No (N)'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-15T16:40:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c66117c5-9bfc-465f-90f7-d4b105f4dd8e'	System	15 Aug 2020 23:40:17
User entered '15 Aug 2020 16:40'	System	15 Aug 2020 23:40:17

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 6'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:43', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:45', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:49', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:52', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:16:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'None (0)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:17:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered 'No (N)'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-16T16:17:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '60992591-6c99-4471-982d-60347858bb52'	System	16 Aug 2020 23:17:26
User entered '16 Aug 2020 16:17'	System	16 Aug 2020 23:17:26

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 7'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:50:59', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:09', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:19', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'None (0)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:22', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered 'No (N)'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-08-17T16:51:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4a10f2ab-f4f8-43f4-8718-620f1d948430'	System	19 Aug 2020 00:57:24
User entered '17 Aug 2020 16:51'	System	19 Aug 2020 00:57:24

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:11:29

US3462111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:10:12

US3462111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '18 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:10:12

US3462111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:10:12

US3462111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered empty.	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:10:12

US3462111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:11:52

US3462111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'I'	System	15 Sep 2020 20:11:52

US3462111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:38
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:12:09

US3462111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:38
User entered '25 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:12:09

US3462111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:12:09

US3462111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:38
User entered empty.	Savannah Peterson (b) (4)	15 Sep 2020 20:12:09

US3462111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:38
User entered 'Yes (Y)'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:12:16

US3462111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	15 Sep 2020 20:12:16

US3462111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:12:34

US3462111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '01 Sep 2020'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:12:34

US3462111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	15 Sep 2020 20:12:34

US3462111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	Savannah Peterson (b) (4)	15 Sep 2020 20:12:34

US3462111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:38
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:12:40

US3462111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	15 Sep 2020 20:12:40

US3462111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:07:50

US3462111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:07:50

US3462111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:07:50

US3462111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'VISIT2'	System	16 Sep 2020 00:07:50

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Pre-Dose (PREDOSE)'		16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '11:58'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '15 Sep 2020 11:58'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '96'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'bpm'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'breaths/min'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '146'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '88'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Post-Dose (POSTDOSE)'		16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '13:20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '15 Sep 2020 13:20'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '86'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'bpm'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'breaths/min'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '146'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '76'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'mmHg'	System	16 Sep 2020 00:10:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:34

US3462111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:10:34

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered empty.	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

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)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) Savannah Peterson (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Feb 2021 01:24:42
User entered '12:42'	Savannah Peterson (b) (4) (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '15 Sep 2020 12:42'	System	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4)	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'ONCE'	System	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 20:13:10

US3462111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:03

US3462111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:03

US3462111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '12:30'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:03

US3462111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '15 Sep 2020 12:30'	System	16 Sep 2020 00:12:03

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '12:32'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '15 Sep 2020 12:32'	System	16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:17:13
User entered 'Yes (Y)'		16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:17:13
User entered '12:32'		16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	09 Oct 2020 20:17:13
User entered '15 Sep 2020 12:32'	System	16 Sep 2020 00:12:24

US3462111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:12:36

US3462111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	16 Sep 2020 00:12:36

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:23:28', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bf03f843-9c65-4e0a-be2d-199120aed4bd'	System	15 Sep 2020 20:24:44
User entered 'Yes (Y)'	System	15 Sep 2020 20:24:44

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:23:42', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bf03f843-9c65-4e0a-be2d-199120aed4bd' User entered '99.1'	System	15 Sep 2020 20:24:44
	System	15 Sep 2020 20:24:44

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:23:49', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bf03f843-9c65-4e0a-be2d-199120aed4bd'	System	15 Sep 2020 20:24:44
User entered 'No (N)'	System	15 Sep 2020 20:24:44

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:24:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'bf03f843-9c65-4e0a-be2d-199120aed4bd'	System	15 Sep 2020 20:24:44
User entered '15 Sep 2020 13:24'	System	15 Sep 2020 20:24:44

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 13:02'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 15:32'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:35:10', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7072b3ed-3f1e-4d34-b6e7-006983b35298'	System	16 Sep 2020 00:38:05
User entered 'Yes (Y)'	System	16 Sep 2020 00:38:05

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7072b3ed-3f1e-4d34-b6e7-006983b35298' User entered '97.8'	System	16 Sep 2020 00:38:05
	System	16 Sep 2020 00:38:05

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7072b3ed-3f1e-4d34-b6e7-006983b35298'	System	16 Sep 2020 00:38:05
User entered 'No (N)'	System	16 Sep 2020 00:38:05

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:41', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7072b3ed-3f1e-4d34-b6e7-006983b35298'	System	16 Sep 2020 00:38:05
User entered '15 Sep 2020 17:36'	System	16 Sep 2020 00:38:05

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 16:27'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 2'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:49:58', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '654d5538-136d-447b-838b-0ecb8407ffd9'	System	11 Dec 2020 15:09:35
User entered 'Yes (Y)'	System	11 Dec 2020 15:09:35

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '654d5538-136d-447b-838b-0ecb8407ffd9'	System	11 Dec 2020 15:09:35
User entered '97.8'	System	11 Dec 2020 15:09:35

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '654d5538-136d-447b-838b-0ecb8407ffd9'	System	11 Dec 2020 15:09:35
User entered 'No (N)'	System	11 Dec 2020 15:09:35

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:16', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '654d5538-136d-447b-838b-0ecb8407ffd9'	System	11 Dec 2020 15:09:35
User entered '16 Sep 2020 17:50'	System	11 Dec 2020 15:09:35

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 3'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:03', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f37a0121-e40e-4f69-b142-993213086198'	System	11 Dec 2020 15:09:47
User entered 'Yes (Y)'	System	11 Dec 2020 15:09:47

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f37a0121-e40e-4f69-b142-993213086198'	System	11 Dec 2020 15:09:47
User entered '97.7'	System	11 Dec 2020 15:09:47

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:14', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f37a0121-e40e-4f69-b142-993213086198'	System	11 Dec 2020 15:09:47
User entered 'No (N)'	System	11 Dec 2020 15:09:47

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f37a0121-e40e-4f69-b142-993213086198'	System	11 Dec 2020 15:09:47
User entered '17 Sep 2020 17:01'	System	11 Dec 2020 15:09:47

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 4'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:37:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5697f70f-fa33-4989-a7a3-bb4ecbd61a48'	System	11 Dec 2020 15:09:49
User entered 'Yes (Y)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:37:41', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5697f70f-fa33-4989-a7a3-bb4ecbd61a48'	System	11 Dec 2020 15:09:49
User entered '97.8'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:37:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5697f70f-fa33-4989-a7a3-bb4ecbd61a48'	System	11 Dec 2020 15:09:49
User entered 'No (N)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:37:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5697f70f-fa33-4989-a7a3-bb4ecbd61a48'	System	11 Dec 2020 15:09:49
User entered '18 Sep 2020 16:37'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 5'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5f6fc266-7f0b-4729-9727-f7459cada882'	System	11 Dec 2020 15:10:01
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:28', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5f6fc266-7f0b-4729-9727-f7459cada882'	System	11 Dec 2020 15:10:01
User entered '98.7'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:34', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5f6fc266-7f0b-4729-9727-f7459cada882'	System	11 Dec 2020 15:10:01
User entered 'No (N)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:39', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '5f6fc266-7f0b-4729-9727-f7459cada882'	System	11 Dec 2020 15:10:01
User entered '19 Sep 2020 18:35'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 6'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:47:51', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '285ccd2f-58e4-4689-b0e3-322dd621eeac'	System	11 Dec 2020 15:10:08
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:08

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:47:57', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '285ccd2f-58e4-4689-b0e3-322dd621eeac'	System	11 Dec 2020 15:10:08
User entered '98.7'	System	11 Dec 2020 15:10:08

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '285ccd2f-58e4-4689-b0e3-322dd621eeac'	System	11 Dec 2020 15:10:08
User entered 'No (N)'	System	11 Dec 2020 15:10:08

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:26', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '285ccd2f-58e4-4689-b0e3-322dd621eeac'	System	11 Dec 2020 15:10:08
User entered '20 Sep 2020 17:48'	System	11 Dec 2020 15:10:08

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 7'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:07:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '349ecf4b-b5e3-4e21-b488-9105a34f1e7d'	System	11 Dec 2020 15:10:15
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:15

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:03', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '349ecf4b-b5e3-4e21-b488-9105a34f1e7d' User entered '97.5'	System	11 Dec 2020 15:10:15
	System	11 Dec 2020 15:10:15

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '349ecf4b-b5e3-4e21-b488-9105a34f1e7d'	System	11 Dec 2020 15:10:15
User entered 'No (N)'	System	11 Dec 2020 15:10:15

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:14', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '349ecf4b-b5e3-4e21-b488-9105a34f1e7d' User entered '22 Sep 2020 04:08'	System	11 Dec 2020 15:10:15
	System	11 Dec 2020 15:10:15

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:24:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4e7d5547-cee0-42ab-a05b-1e3c32558b46'	System	15 Sep 2020 20:25:25
User entered 'None (1)'	System	15 Sep 2020 20:25:25

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:24:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4e7d5547-cee0-42ab-a05b-1e3c32558b46'	System	15 Sep 2020 20:25:25
User entered 'No (N)'	System	15 Sep 2020 20:25:25

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:24:50', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4e7d5547-cee0-42ab-a05b-1e3c32558b46'	System	15 Sep 2020 20:25:25
User entered 'No (N)'	System	15 Sep 2020 20:25:25

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4e7d5547-cee0-42ab-a05b-1e3c32558b46'	System	15 Sep 2020 20:25:25
User entered 'None (1)'	System	15 Sep 2020 20:25:25

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '4e7d5547-cee0-42ab-a05b-1e3c32558b46'	System	15 Sep 2020 20:25:25
User entered '15 Sep 2020 13:25'	System	15 Sep 2020 20:25:25

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 13:02'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 15:32'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:45', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ab042ca4-036e-49b9-9a55-b37b4a20d1ca' User entered 'None (1)'	System	16 Sep 2020 00:38:36
	System	16 Sep 2020 00:38:36

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:48', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ab042ca4-036e-49b9-9a55-b37b4a20d1ca'	System	16 Sep 2020 00:38:36
User entered 'No (N)'	System	16 Sep 2020 00:38:36

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:36:55', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ab042ca4-036e-49b9-9a55-b37b4a20d1ca' User entered 'No (N)'	System	16 Sep 2020 00:38:36
	System	16 Sep 2020 00:38:36

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ab042ca4-036e-49b9-9a55-b37b4a20d1ca' User entered 'None (1)'	System	16 Sep 2020 00:38:36
	System	16 Sep 2020 00:38:36

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:03', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'ab042ca4-036e-49b9-9a55-b37b4a20d1ca' User entered '15 Sep 2020 17:37'	System	16 Sep 2020 00:38:36
	System	16 Sep 2020 00:38:36

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 16:27'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 2'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '370362b7-737d-4e30-a75b-5f1d3012e610'	System	11 Dec 2020 15:09:38
User entered 'None (1)'	System	11 Dec 2020 15:09:38

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '370362b7-737d-4e30-a75b-5f1d3012e610'	System	11 Dec 2020 15:09:38
User entered 'No (N)'	System	11 Dec 2020 15:09:38

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:28', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '370362b7-737d-4e30-a75b-5f1d3012e610'	System	11 Dec 2020 15:09:38
User entered 'No (N)'	System	11 Dec 2020 15:09:38

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '370362b7-737d-4e30-a75b-5f1d3012e610'	System	11 Dec 2020 15:09:38
User entered 'None (1)'	System	11 Dec 2020 15:09:38

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:35', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '370362b7-737d-4e30-a75b-5f1d3012e610'	System	11 Dec 2020 15:09:38
User entered '16 Sep 2020 17:50'	System	11 Dec 2020 15:09:38

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 3'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:26', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a352991b-e049-4cba-a723-fb7bca1e364b'	System	11 Dec 2020 15:09:49
User entered 'None (1)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a352991b-e049-4cba-a723-fb7bca1e364b'	System	11 Dec 2020 15:09:49
User entered 'No (N)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a352991b-e049-4cba-a723-fb7bca1e364b'	System	11 Dec 2020 15:09:49
User entered 'No (N)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a352991b-e049-4cba-a723-fb7bca1e364b'	System	11 Dec 2020 15:09:49
User entered 'None (1)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:39', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a352991b-e049-4cba-a723-fb7bca1e364b'	System	11 Dec 2020 15:09:49
User entered '17 Sep 2020 17:01'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 4'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:37:58', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'd19d7f02-8dde-4ad8-9113-f6fe79326c74'	System	11 Dec 2020 15:10:00
User entered 'None (1)'	System	11 Dec 2020 15:10:00

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'd19d7f02-8dde-4ad8-9113-f6fe79326c74'	System	11 Dec 2020 15:10:00
User entered 'No (N)'	System	11 Dec 2020 15:10:00

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:03', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'd19d7f02-8dde-4ad8-9113-f6fe79326c74'	System	11 Dec 2020 15:10:00
User entered 'No (N)'	System	11 Dec 2020 15:10:00

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:08', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'd19d7f02-8dde-4ad8-9113-f6fe79326c74'	System	11 Dec 2020 15:10:00
User entered 'None (1)'	System	11 Dec 2020 15:10:00

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'd19d7f02-8dde-4ad8-9113-f6fe79326c74'	System	11 Dec 2020 15:10:00
User entered '18 Sep 2020 16:38'	System	11 Dec 2020 15:10:00

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 5'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a46a5ea0-7049-4fac-be39-1aaae5022002'	System	11 Dec 2020 15:10:03
User entered 'None (1)'	System	11 Dec 2020 15:10:03

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:35:57', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a46a5ea0-7049-4fac-be39-1aaae5022002'	System	11 Dec 2020 15:10:03
User entered 'No (N)'	System	11 Dec 2020 15:10:03

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a46a5ea0-7049-4fac-be39-1aaae5022002'	System	11 Dec 2020 15:10:03
User entered 'No (N)'	System	11 Dec 2020 15:10:03

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a46a5ea0-7049-4fac-be39-1aaae5022002'	System	11 Dec 2020 15:10:03
User entered 'None (1)'	System	11 Dec 2020 15:10:03

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:08', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a46a5ea0-7049-4fac-be39-1aaae5022002'	System	11 Dec 2020 15:10:03
User entered '19 Sep 2020 18:36'	System	11 Dec 2020 15:10:03

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 6'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '61adb69a-e67d-478a-a981-62b2e9c26577'	System	11 Dec 2020 15:10:09
User entered 'None (1)'	System	11 Dec 2020 15:10:09

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:35', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '61adb69a-e67d-478a-a981-62b2e9c26577'	System	11 Dec 2020 15:10:09
User entered 'No (N)'	System	11 Dec 2020 15:10:09

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:38', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '61adb69a-e67d-478a-a981-62b2e9c26577'	System	11 Dec 2020 15:10:09
User entered 'No (N)'	System	11 Dec 2020 15:10:09

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:41', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '61adb69a-e67d-478a-a981-62b2e9c26577'	System	11 Dec 2020 15:10:09
User entered 'None (1)'	System	11 Dec 2020 15:10:09

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '61adb69a-e67d-478a-a981-62b2e9c26577'	System	11 Dec 2020 15:10:09
User entered '20 Sep 2020 17:48'	System	11 Dec 2020 15:10:09

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 7'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7da23d48-29bc-4058-b0c3-55ab90933748'	System	11 Dec 2020 15:10:16
User entered 'None (1)'	System	11 Dec 2020 15:10:16

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7da23d48-29bc-4058-b0c3-55ab90933748'	System	11 Dec 2020 15:10:16
User entered 'No (N)'	System	11 Dec 2020 15:10:16

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7da23d48-29bc-4058-b0c3-55ab90933748'	System	11 Dec 2020 15:10:16
User entered 'No (N)'	System	11 Dec 2020 15:10:16

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:27', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7da23d48-29bc-4058-b0c3-55ab90933748'	System	11 Dec 2020 15:10:16
User entered 'None (1)'	System	11 Dec 2020 15:10:16

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:30', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '7da23d48-29bc-4058-b0c3-55ab90933748'	System	11 Dec 2020 15:10:16
User entered '22 Sep 2020 04:08'	System	11 Dec 2020 15:10:16

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:27', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered 'None (0)'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered 'None (0)'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:33', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered 'None (0)'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329' User entered 'None (0)'	System	15 Sep 2020 20:25:54
	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:38', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered 'None (0)'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329' User entered 'None (0)'	System	15 Sep 2020 20:25:54
	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:45', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered 'No (N)'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T13:25:48', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '2fe01e8d-092b-4d64-9655-94b928dd3329'	System	15 Sep 2020 20:25:54
User entered '15 Sep 2020 13:25'	System	15 Sep 2020 20:25:54

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 13:02'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 15:32'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:09', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:10', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:12', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:17', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'None (0)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:24', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered 'No (N)'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-15T17:37:26', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c19fe2ff-ac62-4663-9a80-0dea6291d050'	System	11 Dec 2020 15:09:32
User entered '15 Sep 2020 17:37'	System	11 Dec 2020 15:09:32

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '15 Sep 2020 16:27'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 2'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:41', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:43', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:45', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:49', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'None (0)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:52', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered 'No (N)'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-16T17:50:55', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8febd744-bbe4-4c24-95a2-314355f9c371'	System	11 Dec 2020 15:09:42
User entered '16 Sep 2020 17:50'	System	11 Dec 2020 15:09:42

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 3'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:43', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:45', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:49', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:51', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:53', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'None (0)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:01:58', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered 'No (N)'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-17T17:02:01', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e0786f12-46e9-4b3f-a39b-dc42ebfea8c5'	System	11 Dec 2020 15:09:49
User entered '17 Sep 2020 17:02'	System	11 Dec 2020 15:09:49

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 4'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:15', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:17', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:19', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:23', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'None (0)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:30', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered 'No (N)'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-18T16:38:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '014f620f-bc59-4be0-9c1f-35da0a6ddab0'	System	11 Dec 2020 15:10:01
User entered '18 Sep 2020 16:38'	System	11 Dec 2020 15:10:01

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 5'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a'	System	11 Dec 2020 15:10:05
User entered 'None (0)'	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:18', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a' User entered 'None (0)'	System	11 Dec 2020 15:10:05
	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a'	System	11 Dec 2020 15:10:05
User entered 'None (0)'	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:26', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a'	System	11 Dec 2020 15:10:05
User entered 'None (0)'	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a' User entered 'None (0)'	System	11 Dec 2020 15:10:05
	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:32', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a'	System	11 Dec 2020 15:10:05
User entered 'None (0)'	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a'	System	11 Dec 2020 15:10:05
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-19T18:36:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '8a001066-937e-46eb-b726-8eb141bd778a' User entered '19 Sep 2020 18:36'	System	11 Dec 2020 15:10:05
	System	11 Dec 2020 15:10:05

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 6'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:56', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'No interference with activity (1)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:48:59', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'None (0)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:02', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'None (0)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:05', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'None (0)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'None (0)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:09', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'None (0)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:20', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-20T17:49:23', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'af27ea66-08f0-4d98-bedb-0f6a1abfa4fc'	System	11 Dec 2020 15:10:14
User entered '20 Sep 2020 17:49'	System	11 Dec 2020 15:10:14

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
Data entry locked.	System	15 Sep 2020 20:13:10
User entered 'Day 7'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:35', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:37', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:40', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:42', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:46', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'None (0)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:54', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered 'Yes (Y)'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-09-22T04:08:57', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a149dc07-94bc-4f26-bcf0-d0747805f60c'	System	11 Dec 2020 15:10:17
User entered '22 Sep 2020 04:08'	System	11 Dec 2020 15:10:17

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:13:10

US3462111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:06
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:13:10

US3462111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:32:37

US3462111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:32:37

US3462111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:32:37

US3462111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:32:37

US3462111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:32:42

US3462111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	13 Oct 2020 23:32:42

US3462111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:33:30

US3462111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:33:30

US3462111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:33:30

US3462111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:33:30

US3462111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:33:34

US3462111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'I'	System	13 Oct 2020 23:33:34

US3462111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:02

US3462111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:02

US3462111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:02

US3462111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:02

US3462111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:06

US3462111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'I'	System	13 Oct 2020 23:34:06

US3462111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:35

US3462111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:35

US3462111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:35

US3462111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'VISIT3'	System	13 Oct 2020 23:34:35

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered empty.	System	13 Oct 2020 23:34:45

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20

US3462111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20

US3462111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:53

US3462111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:34:53

US3462111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:35:06

US3462111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:35:06

US3462111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered '09:00'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:35:06

US3462111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '13 Oct 2020 09:00'	System	13 Oct 2020 23:35:06

US3462111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 23:35:10

US3462111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered '1'	System	13 Oct 2020 23:35:10

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 64'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 71'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 78'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 92'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered 'Day 99'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 17:11:29

US3462111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:18:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:48:12
Data entry locked.	System	11 Aug 2020 17:11:29
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 17:11:29

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-11T07:09:55', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '0d9a7527-fd44-441c-8ecc-0965077c7008'	System	11 Dec 2020 15:10:52
User entered 'No (N)'	System	11 Dec 2020 15:10:52

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-11T07:10:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '0d9a7527-fd44-441c-8ecc-0965077c7008'	System	11 Dec 2020 15:10:52
User entered 'No (N)'	System	11 Dec 2020 15:10:52

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-11T07:10:08', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '0d9a7527-fd44-441c-8ecc-0965077c7008'	System	11 Dec 2020 15:10:52
User entered '11 Dec 2020 07:10:08'	System	11 Dec 2020 15:10:52

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-17T08:02:35', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e832a8bc-c889-49a5-b8f9-10671a2cd696'	System	25 Dec 2020 01:21:21
User entered 'No (N)'	System	25 Dec 2020 01:21:21

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-17T08:02:38', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e832a8bc-c889-49a5-b8f9-10671a2cd696'	System	25 Dec 2020 01:21:21
User entered 'No (N)'	System	25 Dec 2020 01:21:21

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-17T08:02:42', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'e832a8bc-c889-49a5-b8f9-10671a2cd696'	System	25 Dec 2020 01:21:21
User entered '17 Dec 2020 08:02:42'	System	25 Dec 2020 01:21:21

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-24T17:21:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b03d9a87-640a-4094-8eaf-6ffc4e0743f6'	System	25 Dec 2020 01:21:42
User entered 'No (N)'	System	25 Dec 2020 01:21:42

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-24T17:21:34', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b03d9a87-640a-4094-8eaf-6ffc4e0743f6'	System	25 Dec 2020 01:21:42
User entered 'No (N)'	System	25 Dec 2020 01:21:42

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2020-12-24T17:21:37', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'b03d9a87-640a-4094-8eaf-6ffc4e0743f6'	System	25 Dec 2020 01:21:42
User entered '24 Dec 2020 17:21:37'	System	25 Dec 2020 01:21:42

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-01T10:43:26', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c20a2c75-ea87-4bbb-a01f-dacce4003315'	System	06 Jan 2021 14:56:11
User entered 'No (N)'	System	06 Jan 2021 14:56:11

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-01T10:43:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c20a2c75-ea87-4bbb-a01f-dacce4003315'	System	06 Jan 2021 14:56:11
User entered 'No (N)'	System	06 Jan 2021 14:56:11

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-01T10:43:37', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'c20a2c75-ea87-4bbb-a01f-dacce4003315'	System	06 Jan 2021 14:56:11
User entered '01 Jan 2021 10:43:37'	System	06 Jan 2021 14:56:11

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-07T06:35:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'fcc971c7-56ae-4ad9-a3b3-91ee32761b48'	System	07 Jan 2021 14:36:25
User entered 'No (N)'	System	07 Jan 2021 14:36:25

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-07T06:35:47', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'fcc971c7-56ae-4ad9-a3b3-91ee32761b48'	System	07 Jan 2021 14:36:25
User entered 'No (N)'	System	07 Jan 2021 14:36:25

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-07T06:35:50', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'fcc971c7-56ae-4ad9-a3b3-91ee32761b48' User entered '07 Jan 2021 06:35:50'	System	07 Jan 2021 14:36:25
	System	07 Jan 2021 14:36:25

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-15T12:49:44', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a1250c36-def-4970-ab39-85cdd6141787'	System	15 Jan 2021 20:50:17
User entered 'No (N)'	System	15 Jan 2021 20:50:17

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-15T12:49:48', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a1250c36-def-4970-ab39-85cdd6141787'	System	15 Jan 2021 20:50:17
User entered 'No (N)'	System	15 Jan 2021 20:50:17

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-15T12:49:52', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a1250c36-def-4970-ab39-85cdd6141787'	System	15 Jan 2021 20:50:17
User entered '15 Jan 2021 12:49:52'	System	15 Jan 2021 20:50:17

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-21T08:52:11', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f0a9001c-6ac1-40b4-b3e0-42506a6b70fa' User entered 'No (N)'	System	21 Jan 2021 17:22:19
	System	21 Jan 2021 17:22:19

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-21T08:52:13', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f0a9001c-6ac1-40b4-b3e0-42506a6b70fa'	System	21 Jan 2021 17:22:19
User entered 'No (N)'	System	21 Jan 2021 17:22:19

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-21T08:52:17', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'f0a9001c-6ac1-40b4-b3e0-42506a6b70fa'	System	21 Jan 2021 17:22:19
User entered '21 Jan 2021 08:52:17'	System	21 Jan 2021 17:22:19

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-28T07:30:55', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '469fb088-bd79-4c72-ace4-5212c883bddf'	System	28 Jan 2021 15:31:17
User entered 'No (N)'	System	28 Jan 2021 15:31:17

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-28T07:31:04', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '469fb088-bd79-4c72-ace4-5212c883bddf' User entered 'No (N)'	System	28 Jan 2021 15:31:17
	System	28 Jan 2021 15:31:17

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-01-28T07:31:07', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '469fb088-bd79-4c72-ace4-5212c883bddf' User entered '28 Jan 2021 07:31:07'	System	28 Jan 2021 15:31:17
	System	28 Jan 2021 15:31:17

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-04T19:41:22', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a333831b-973c-4f01-b642-9a3add8bfd23'	System	05 Feb 2021 03:41:36
User entered 'No (N)'	System	05 Feb 2021 03:41:36

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-04T19:41:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a333831b-973c-4f01-b642-9a3add8bfd23'	System	05 Feb 2021 03:41:36
User entered 'No (N)'	System	05 Feb 2021 03:41:36

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-04T19:41:31', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: 'a333831b-973c-4f01-b642-9a3add8bfd23'	System	05 Feb 2021 03:41:36
User entered '04 Feb 2021 19:41:31'	System	05 Feb 2021 03:41:36

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-11T06:39:17', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6a8ab878-ecb2-43d2-b824-78bba89a1f7d'	System	18 Feb 2021 14:43:13
User entered 'No (N)'	System	18 Feb 2021 14:43:13

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-11T06:39:21', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6a8ab878-ecb2-43d2-b824-78bba89a1f7d'	System	18 Feb 2021 14:43:13
User entered 'No (N)'	System	18 Feb 2021 14:43:13

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-11T06:39:25', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '6a8ab878-ecb2-43d2-b824-78bba89a1f7d'	System	18 Feb 2021 14:43:13
User entered '11 Feb 2021 06:39:25'	System	18 Feb 2021 14:43:13

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-18T06:43:29', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '96807516-032a-45d0-843a-d8961a773542'	System	18 Feb 2021 14:43:38
User entered 'No (N)'	System	18 Feb 2021 14:43:38

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-18T06:43:33', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '96807516-032a-45d0-843a-d8961a773542'	System	18 Feb 2021 14:43:38
User entered 'No (N)'	System	18 Feb 2021 14:43:38

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-18T06:43:36', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '96807516-032a-45d0-843a-d8961a773542'	System	18 Feb 2021 14:43:38
User entered '18 Feb 2021 06:43:36'	System	18 Feb 2021 14:43:38

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

[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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-25T06:48:37-08:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95dbc68e-37fb-4a47-bb89-c84598212f54'	System	25 Feb 2021 14:49:16
User entered 'No (N)'	System	25 Feb 2021 14:49:16

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

Have you been exposed to someone with 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 (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-25T06:48:39-08:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95dbc68e-37fb-4a47-bb89-c84598212f54'	System	25 Feb 2021 14:49:16
User entered 'No (N)'	System	25 Feb 2021 14:49:16

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AAC15C17-EA8D-4D26-BEC8-CBE83D801822)', Time: '2021-02-25T06:48:42-08:00', User OID: 'PatientReportedOutcome (US3462111)', ODM File OID: '95dbc68e-37fb-4a47-bb89-c84598212f54'	System	25 Feb 2021 14:49:16
User entered '25 Feb 2021 14:48:42'	System	25 Feb 2021 14:49:16

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:48:12

US3462111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:44

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:48:12

**US3462111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:48:12
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:48:12

US3462111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:41:23

US3462111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:41:04
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:41:30
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Nov 2020 23:41:23
User entered '04 Nov 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:41:23

US3462111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	05 Nov 2020 23:41:23

US3462111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 23:41:23

US3462111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:41:37

US3462111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:20
User entered 'I'	System	05 Nov 2020 23:41:37

US3462111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:30:54
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Updated Missing Data' (Site from DM).		09 Feb 2021 18:32:31
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).		08 Feb 2021 22:56:07
User entered 'Yes (Y)'		09 Dec 2020 17:09:41

US3462111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 15Jan2021. 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 on 15Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Updated Missing Data' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:30:56
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 15Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '9 Dec 2020'		09 Feb 2021 18:32:38
		08 Feb 2021 20:04:19
		09 Dec 2020 17:09:41

US3462111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:09:41

US3462111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:09:41

US3462111

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:09:51

US3462111

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered 'I'	System	09 Dec 2020 17:09:51

US3462111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:34

US3462111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:34

US3462111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:34

US3462111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:34

US3462111

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:43:40

US3462111

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered 'I'	System	22 Mar 2021 19:43:40

US3462111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:50

US3462111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:43:50

US3462111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:43:50

US3462111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Mar 2021 19:43:50

US3462111

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:43:55

US3462111

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered 'I'	System	22 Mar 2021 19:43:55

US3462111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User closed query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		02 Apr 2021 12:28:10
Query 'Per CDM: Vital Signs page has not been entered, please complete.' answered with 'updated' (Site from DM).		01 Apr 2021 19:08:47
User opened query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		30 Mar 2021 10:08:29
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:07

US3462111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:07

US3462111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:07

US3462111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered 'VISIT4'	System	22 Mar 2021 19:44:07

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered empty.	System	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered empty.	System	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered empty.	System	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered empty.	System	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered empty.	System	01 Apr 2021 16:36:29

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31

US3462111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31

US3462111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:12

US3462111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:12

US3462111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:44:30

US3462111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:30

US3462111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '09:02'	(b) (4) (d) (4), (b) (6)	22 Mar 2021 19:44:30

US3462111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered '17 Mar 2021 09:02'	System	22 Mar 2021 19:44:30

US3462111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:44:36

US3462111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:31
User entered '1'	System	22 Mar 2021 19:44:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:33:11

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (d) (4), (b) (6)	09 Feb 2021 18:33:11

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:33:11

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 18:33:11

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:35
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5 please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'updated data, Per source document Date of un-blinding is 15 Jan 2021' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 14:46:31
	(b) (4), (b) (6)	07 Apr 2021 20:43:20
	(b) (4), (b) (6)	07 Apr 2021 20:42:59
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 20:42:59
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 20:09:31

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:16
User entered '0' WR# 5295537	(b) (4)	System 10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:46:09

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:16
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:46:09

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Placebo (Placebo)'	(b) (4) (o) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query "Will participant receive mRNA-1273?" is missing. Please reconcile.' (Site from System).	(b) (4) System	09 Feb 2021 18:37:59
Query "Will participant receive mRNA-1273?" is missing. Please reconcile.' answered by data change (Site from System).	System	09 Feb 2021 18:37:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:37:59
User opened query "Will participant receive mRNA-1273?" is missing. Please reconcile.' (Site from System).	System	09 Feb 2021 18:37:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '1'	System	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '1'	System	09 Feb 2021 18:37:59
User entered empty.	System	09 Feb 2021 18:37:54

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '156' cm	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '62.6' kg	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '25.72321'	System	09 Feb 2021 18:40:08
DataPoint set to visible.	System	09 Feb 2021 18:37:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '156' cm	(b) (4) (p) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '62.6' kg	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '25.72321'	System	09 Feb 2021 18:40:08
DataPoint set to visible.	System	09 Feb 2021 18:37:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User accepted default value 'Pre-Dose (PREDOSE)'		09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '09:40'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '15 Jan 2021 09:40'	System	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:32:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:36:07
User entered 'Other (Other)' reason for change: Data Entry Error		22 Apr 2021 18:36:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:32:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:36:07
User entered 'TYMPANIC' reason for change: Data Entry Error		22 Apr 2021 18:36:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '95'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'bpm'	System	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '18'	(b) (4) (o) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'breaths/min'	System	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '144'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '84'	(b) (4) (o) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '156' cm	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '62.6' kg	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:08

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '25.72321'	System	09 Feb 2021 18:40:08
DataPoint set to visible.	System	09 Feb 2021 18:37:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User accepted default value 'Post-Dose (POSTDOSE)'		09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '11:05'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '15 Jan 2021 11:05'	System	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:32:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:36:07
User entered 'Other (Other)' reason for change: Data Entry Error		22 Apr 2021 18:36:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:32:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:36:07
User entered 'TYMPANIC' reason for change: Data Entry Error		22 Apr 2021 18:36:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '91'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'bpm'	System	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '14'	(b) (4) (p) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'breaths/min'	System	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '141'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '91'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	09 Feb 2021 18:40:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (o) (4), (b) (6)	09 Feb 2021 18:41:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

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)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mRNA-1273'	System	09 Feb 2021 18:41:36
DataPoint set to visible.	System	09 Feb 2021 18:37:59

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '10:33'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '15 Jan 2021 10:33'	System	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'ONCE'	System	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 18:41:36

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	09 Feb 2021 18:38:30
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		09 Feb 2021 18:38:30
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:38:30
User closed query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:38:30
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:38:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:38:19
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:38:19
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:38:19
User entered '15 Jan 2020'	(b) (4), (b) (6)	09 Feb 2021 18:38:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '09:35'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '15 Jan 2021 09:35'	System	09 Feb 2021 18:38:30
User entered '15 Jan 2020 09:35'	System	09 Feb 2021 18:38:19

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:45

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:45

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '09:26'	(b) (4) (p) (4), (b) (6)	09 Feb 2021 18:38:45

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '15 Jan 2021 09:26'	System	09 Feb 2021 18:38:45

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:38:50

US3462111

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '1'	System	09 Feb 2021 18:38:50

US3462111

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:37:24

US3462111

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:02:04
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per source document Date is correct unknow why the call was done out of window ' (Site from System).		22 Mar 2021 19:37:55
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Mar 2021 19:37:24
User entered '02 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:37:24

US3462111

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:37:24

US3462111

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:37:24

US3462111

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:38:07

US3462111

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'I'	System	22 Mar 2021 19:38:07

US3462111

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '1'	System	22 Mar 2021 19:38:07
DataPoint set to visible.	System	22 Mar 2021 19:38:07

US3462111

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:38:38

US3462111

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:38:38

US3462111

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:38:38

US3462111

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'OLD29'	System	22 Mar 2021 19:38:38

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User accepted default value 'Pre-Dose (PREDOSE)'		22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '13:58'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '10 Feb 2021 13:58'	System	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:10:38
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS ' (Site from System).		22 Mar 2021 19:40:08
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Mar 2021 19:39:56
User entered '96.6' F	(b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '76'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'bpm'	System	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '18'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'breaths/min'	System	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '140'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '86'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	22 Mar 2021 19:39:56

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User accepted default value 'Post-Dose (POSTDOSE)'		22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '10 Feb 2021'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '15:49'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '10 Feb 2021 15:49'	System	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Oral (Oral)'	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '80'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'bpm'	System	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '12'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'breaths/min'	System	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '146'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '84'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mmHg'	System	22 Mar 2021 19:40:44

US3462111

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:13

US3462111

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:13

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

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)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'mRNA-1273'	System	22 Mar 2021 19:41:36
DataPoint set to visible.	System	22 Mar 2021 19:38:07

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '15:18'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '10 Feb 2021 15:18'	System	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'ONCE'	System	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 19:41:36

US3462111

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:41:41

US3462111

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'I'	System	22 Mar 2021 19:41:41

US3462111

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:00

US3462111

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:00

US3462111

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:00

US3462111

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:00

US3462111

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:05

US3462111

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'I'	System	22 Mar 2021 19:42:05

US3462111

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:24

US3462111

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:24

US3462111

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:24

US3462111

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered 'OLD57'	System	22 Mar 2021 19:42:24

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered empty.	System	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered empty.	System	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered empty.	System	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (p) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered empty.	System	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered empty.	System	22 Mar 2021 19:42:32

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56

US3462111

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56

US3462111

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:41

US3462111

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:41

US3462111

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:54

US3462111

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	25 Mar 2021 22:11:44
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 19:43:01
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		22 Mar 2021 19:43:01
User entered '17 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:43:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 19:42:54
User entered '17 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 19:42:54

US3462111

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:11:44
User entered '09:02'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:42:54

US3462111

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:21:56
User entered '17 Mar 2021 09:02'	System	22 Mar 2021 19:43:01
User entered '17 Feb 2021 09:02'	System	22 Mar 2021 19:42:54

US3462111

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:12:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:25
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 20:25:45

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
Reviewed for Safety.		25 Sep 2020 15:53:51
User entered 'USA-US093-2020-mRNA-1273-P301000004'	System	25 Sep 2020 15:53:45
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 15:53:45

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).		13 Nov 2020 15:02:00
Query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'patient did not experience any covid symptoms, and no deviation noted' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:45:01
User opened query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:28:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Laryngeal spasm, oedema and obstruction, PT: Laryngeal oedema, LLT: Laryngeal edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:04:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:04:35
Data point term sent to Coder	System	24 Sep 2020 21:04:00
User entered 'Laryngeal Edema'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '19 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Sep 2020 21:04:53
User entered empty; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:04:53
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Sep 2020 21:03:05
User entered '08:00'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:04:53
User entered '19 Sep 2020 08:00'	System	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '24 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Sep 2020 21:04:53
User entered empty; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:04:53
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Sep 2020 21:03:05
User entered '12:00'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:04:53
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Grade 4 (Grade 4)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Sep 2020 21:04:14
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Sep 2020 21:03:05
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	24 Sep 2020 21:04:14
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	24 Sep 2020 21:04:14
User entered '1' reason for change: Data Entry Error	Savannah Peterson (b) (4)	24 Sep 2020 21:04:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	24 Sep 2020 21:03:05
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '19 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '20 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 21:04:14
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	24 Sep 2020 21:04:14
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 21:03:05
User entered '1'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Not Applicable (NOT APPLICABLE)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '1'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered '0'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:21
User entered empty.	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4) (D) (4), (b) (6)	05 Feb 2021 18:32:18
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Request has been made , no records have been sent to us ' (Site from Safety).		04 Feb 2021 18:55:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		06 Jan 2021 14:45:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).		06 Jan 2021 14:45:37
DataPoint Verified.		18 Nov 2020 20:17:21
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).		13 Nov 2020 19:15:15
User closed query 'Per DM CLR: Narrative contains some medications. Please make sure that all treatments are recorded in the Con Med eCRF. Update and reconcile as appropriate. ' (Site from DM).		13 Nov 2020 15:02:39

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update Rave with lisinopril stop date.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 23:37:18
User closed query 'PV Query: Please update CM eCRF to include stop dates for medications, and addition of treatment medications.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 23:37:14
User closed query 'PV Query: Please confirm that treatment included systemic steroids and asthma medications.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 23:37:10
User closed query 'PV Query: Please confirm whether the subject had any associated skin reactions (i.e. rash, pruritus).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 23:36:56
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)	06 Nov 2020 23:36:49
Query 'Per DM CLR: Narrative contains some medications. Please make sure that all treatments are recorded in the Con Med eCRF. Update and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:46:37
Query 'PV Query: Please update Rave with lisinopril stop date.' answered with 'updated' (Site from Safety).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:46:32
Query 'PV Query: Please update CM eCRF to include stop dates for medications, and addition of treatment medications.' answered with 'updated' (Site from Safety).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:46:23
Query 'PV Query: Please confirm that treatment included systemic steroids and asthma medications.' answered with 'systemic steroids used to treat ' (Site from Safety).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:46:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records requested. will update when received' (Site from Safety).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:45:58
Query 'PV Query: Please confirm whether the subject had any associated skin reactions (i.e. rash, pruritus).' answered with 'no rashes reported' (Site from Safety).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:45:42

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative contains some medications. Please make sure that all treatments are recorded in the Con Med eCRF. Update and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:02:35
User opened query 'PV Query: Please update Rave with lisinopril stop date.' (Site from Safety).		02 Oct 2020 17:47:39
User opened query 'PV Query: Please update CM eCRF to include stop dates for medications, and addition of treatment medications.' (Site from Safety).		02 Oct 2020 17:46:39
User opened query 'PV Query: Please confirm that treatment included systemic steroids and asthma medications.' (Site from Safety).		02 Oct 2020 17:46:23
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).		02 Oct 2020 17:46:03
User opened query 'PV Query: Please confirm whether the subject had any associated skin reactions (i.e. rash, pruritus).' (Site from Safety).		02 Oct 2020 17:45:51
User entered '57 year old woman with Asthma and PMH of Hypertension consented and randomized for Moderna on 11Aug2020 and received visit 2 dose on 15Sep2020. Patient had acute Laryngeal Edema episode while doing outdoor yardwork on 08:00 on 19SEP2020. She was admitted to local hospital ICU, and treatment with discontinuation of con-med Lisinopril 5 mg daily, as well with systemic steroids and her regular asthma medications. The laryngeal edema improved by 20SEP2020 and patient was discharged to home on 5 days of Prednisone completed on 24SEP2020 by 12:00. She is now using an alternate blood pressure medication Olmesartan5 mg daily. The physicians treating patient attributed laryngeal edema episode to her con-med Lisinopril 5mg daily, and discontinued this medication on 20SEP2020. Lisinopril had been used since September 2018. The SAE was felt not-related to the study vaccine. All history from patient phone call at 15:00 on 23SEP2020. SAE is reported on eCRF today.'	Savannah Peterson (b) (4) (b) (4)	24 Sep 2020 21:03:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1949 of 2209

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:03:05

---

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:03:05

---

US3462111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 21:03:05

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:12:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:17:56
User entered 'Yes (Y)'		16 Sep 2020 00:13:13

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 00:15:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 00:15:52
Data point term sent to Coder	System	16 Sep 2020 00:15:01
User entered 'ADVAIR 250/50'	(b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:30:15
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.		09 Oct 2020 20:17:42
' answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:17:35
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).		03 Oct 2020 11:57:48
User entered 'Yes (Y)'		16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'ASTHMA'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '27 Nov 2018'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	(b) (4), (b) (6)

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:14:15

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	16 Sep 2020 00:14:15

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:14:15

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:14:15

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 00:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 00:16:53
Data point term sent to Coder User entered 'ALBUTEROL'	System (b) (4), (b) (6)	16 Sep 2020 00:16:04 16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:30:19
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.		09 Oct 2020 20:17:59
' answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:17:52
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).		03 Oct 2020 11:58:02
User entered 'Yes (Y)'		16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Oct 2020 11:57:58
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		03 Oct 2020 11:57:55
User entered 'ASTHMA'		16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '180'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 1982'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:15:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:15:37

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:15:37

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:15:37

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:17:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:17:57
Data point term sent to Coder	System	16 Sep 2020 00:17:05
User entered 'LISINOPRIL'	(b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:30:24
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.		09 Oct 2020 20:18:46
' answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:18:36
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. '(Site from DM).		03 Oct 2020 11:58:10
User entered 'Yes (Y)'		16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '5'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN Sep 2018'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 23:58:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '19 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 23:58:29
	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User entered '1'	System	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User entered '1'	System	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:21
User entered '804 (804)'	System	16 Sep 2020 00:16:07

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:17:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:17:57
Data point term sent to Coder	System	16 Sep 2020 00:17:05
User entered 'VITAMIN D3'	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:18:57
User entered 'No (N)'		16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:00:49
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:52:58
User entered '5000' reason for change: Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:52:37
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 20:48:33
User entered '1'		16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 23:52:37
	(b) (4)	
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:16:38

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:40:44**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:16:38

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:16:38

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:16:38

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:18:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 00:18:58
Data point term sent to Coder User entered 'VITAMIN B12'	System (b) (4), (b) (6)	16 Sep 2020 00:18:08 16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM). Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:18:55 04 Feb 2021 18:56:56 04 Feb 2021 18:56:48
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM). User entered 'No (N)'		06 Jan 2021 17:05:09 16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:00:53
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:54:36
User entered '1000' reason for change: Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:54:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 20:48:49
User entered '1'		16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 23:54:29
	(b) (4)	
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:16

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:17:16

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:17:16

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:17:16

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 00:18:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 00:18:57
Data point term sent to Coder	System	16 Sep 2020 00:18:05
User entered 'MAGNESIUM'	(b) (4), (b) (6) [REDACTED] [REDACTED]	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (d) (4), (b) (6)	09 Oct 2020 20:19:16
User entered 'No (N)'		16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'SUPPLEMENT'	(b) (4) (d) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:00:58
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:55:28
User entered '400' reason for change: Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:55:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 20:49:05
User entered '1'		16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 23:55:22
	(b) (4)	
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	(b) (4), (b) (6)

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:17:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:17:49

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:17:49

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:17:49

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 00:19:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 00:19:52
Data point term sent to Coder	System	16 Sep 2020 00:19:10
User entered 'BIOTIN'	(b) (4), (b) (6) [REDACTED] [REDACTED]	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:19:29
User entered 'No (N)'		16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:19:00
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'No other information know' (Site from DM).		23 Nov 2020 18:10:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		20 Nov 2020 09:17:14
User entered '1'		16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:22

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:40:44**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:18:22

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:18:22

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:18:22

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 00:19:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 00:19:53
Data point term sent to Coder	System	16 Sep 2020 00:19:08
User entered 'IBUPROFEN'	(b) (4), (b) (6) [REDACTED] [REDACTED]	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4) (d) (4), (b) (6)	23 Oct 2020 11:30:36
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.		09 Oct 2020 20:19:52
' answered with 'UPDATED' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:19:43
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate. ' (Site from DM).		03 Oct 2020 11:58:34
User entered 'Yes (Y)'		16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'OCCASIONAL HEADACHES'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '200'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:18:57

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:40:44**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:18:57

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:18:57

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:18:57

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CIMICIFUGA RACEMOSA, PRODUCTSYNONYM: BLACK COHOSH [CIMICIFUGA RACEMOSA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 02:06:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 02:06:57
Data point term sent to Coder	System	16 Sep 2020 00:20:11
User entered 'BLACK COHASH'	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:20:09
User entered 'No (N)'		16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '11 Apr 2019'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:19:49

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:44**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:19:49

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 00:19:49

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 00:19:49

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 04:56:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 04:56:52
Data point term sent to Coder	System	16 Sep 2020 00:22:14
User entered 'TYLENOL PM' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 00:21:26
Data point term sent to Coder	System	16 Sep 2020 00:21:13
User entered 'TYLENO PM'	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:20:24
User entered 'Yes (Y)'		16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:01:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:48:02
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:58:46
User entered 'OCCASIONAL INSOMNIA'		16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
	(b) (4)	
User entered 'UN Apr 2020'	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 00:20:37

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:40:44**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:20:37

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:20:37

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 00:20:37

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:58:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:58:31
Data point term sent to Coder	System	05 Nov 2020 23:56:59
User entered 'olmesartan'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'hypertension'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered '5'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'mg (mg)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'once daily (QD)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'Oral (ORAL)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered '22 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:00
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:56:40

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 23:56:40

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 23:56:40

---

US3462111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:40:44**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 23:56:40

---

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:29
Data point term sent to Coder	System	05 Nov 2020 23:57:59
User entered 'prednisone'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 23:57:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 23:57:55
User entered 'No (N)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 23:57:55
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 23:57:48
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'laryngeal edema'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered '20'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'mg (mg)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'once daily (QD)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'Oral (ORAL)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered '19 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered '24 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:19:04
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User entered '1'	System	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User entered '1'	System	05 Nov 2020 23:57:48

US3462111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:57:27
User entered '804 (804)'	System	05 Nov 2020 23:57:48

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:09
User entered 'USA-US093-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Edward'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Kerwin'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		06 Nov 2020 23:37:42
User entered 'US'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '2'	(b) (4)	06 Nov 2020 23:37:53
User entered '1'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:09
User entered 'USA-US093-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Edward'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Kerwin'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		06 Nov 2020 23:37:42
User entered 'US'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '2'	(b) (4)	06 Nov 2020 23:37:53
User entered '1'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
User entered '25/Sep/2020 15:54'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:44

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		06 Nov 2020 23:37:42
User entered '1'		25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:09
User entered 'USA-US093-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Yes (Y)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'No (N)'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Edward'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		25 Sep 2020 15:54:12
User entered 'Kerwin'	System	25 Sep 2020 15:53:45

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
Reviewed for Safety.		06 Nov 2020 23:37:42
User entered 'US'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
User entered '2'	(b) (4)	06 Nov 2020 23:37:53
User entered '1'	System	25 Sep 2020 15:54:21

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
User entered '06/Nov/2020 23:37'	System	06 Nov 2020 23:37:53

US3462111

Folder: SAE USA-US093-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:44

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:13:18
User entered '1'		06 Nov 2020 23:37:53