

US3392112 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:24:17

All time stamps listed in this document are displayed in GMT

US3392112

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

---

[Participant ID](#)

US3392112

---

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

---

---

US3392112

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:12:15

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3392112

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3392112

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3392112

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3392112

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3392112

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Condition	ANEMIA
Start date (dd MMM yyyy)	UN JUL 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	



US3392112

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Condition	HERPES SIMPLEX
Start date (dd MMM yyyy)	UN MAR 1951
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1951
Start Year (derived)	1951
Stop Month and Year (derived)	
Stop Year (derived)	

US3392112

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JAN 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3392112

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392112

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

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



US3392112

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:12:15

Generated On: 09 Jun 2021 17:24:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:42
Height (xxx.x)	58.0 in
Weight (xxx.x)	168.9 lb
BMI (xxx.x)	35.37395 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3392112

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3392112

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 03:12:14

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*) 28 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 MAY 2005

Date of last menstruation unknown False

US3392112

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:12:15

Generated On: 09 Jun 2021 17:24:17

---

**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** RETIRED

---

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

**No Risk Identified** False

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

US3392112

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:12:15

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188957

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 ☒

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Height	ND - Not Done
Weight	ND - Not Done



US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:42
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:11
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3392112

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 15:40

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

US3392112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	15:15 (24 HR)
Collection date and time (derived)	28 AUG 2020 15:15

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:10	28 AUG 2020 15:10
Nasopharyngeal Swab 2	No		

US3392112

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:51:21

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 28 AUG 2020 16:17

PC Open Date & Time 28 AUG 2020 16:00

PC Close Date & Time 28 AUG 2020 18:30



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**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 97.4 °F

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

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

PC Time Stamp	29 AUG 2020 10:48
PC Open Date & Time	28 AUG 2020 19:25
PC Close Date & Time	29 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 12:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 10:56

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 SEP 2020 11:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**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

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 SEP 2020 14:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:56

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**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

28 AUG 2020 16:18

PC Open Date & Time

28 AUG 2020 16:00

PC Close Date & Time

28 AUG 2020 18:30



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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

63

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

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

29 AUG 2020 10:54

PC Open Date & Time

28 AUG 2020 19:25

PC Close Date & Time

29 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

64

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 10:57

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 11:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 14:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 13:56

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**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 ☐



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:19
PC Open Date & Time	28 AUG 2020 16:00
PC Close Date & Time	28 AUG 2020 18:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**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 ☐

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 10:56
PC Open Date & Time	28 AUG 2020 19:25
PC Close Date & Time	29 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 3359

EAB) (1725)

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3359

EAB) (1725)

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 10:58
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3359

EAB) (1725)



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 11:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 3359

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3359

EAB) (1725)

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 14:47
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

61 of 3359

EAB) (1725)

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

		Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 13:57	
PC Open Date & Time	03 SEP 2020 12:00	
PC Close Date & Time	04 SEP 2020 11:59	

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 SEP 2020 18:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

06 SEP 2020 14:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

---

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 09:58

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 18:19
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 14:17
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 12:00
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 09:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3392112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:05:02

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:05:02

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:31:32

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:31:32

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:12:04

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:12:04

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	12:54 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:54
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3392112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 SEP 2020

What was the treatment time? (00:00-23:59) 13:29 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 13:29

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

US3392112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

22 SEP 2020 13:05

US3392112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:00	22 SEP 2020 13:00
Nasopharyngeal Swab 2	No		

US3392112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:40:14

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 13:55

PC Open Date & Time

22 SEP 2020 13:49

PC Close Date & Time

22 SEP 2020 16:19



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**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 96.1 °F

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

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

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

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

PC Time Stamp 22 SEP 2020 21:16

PC Open Date & Time 22 SEP 2020 17:14

PC Close Date & Time 23 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**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	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	24 SEP 2020 09:06
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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):

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

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

PC Time Stamp 24 SEP 2020 13:38

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

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

PC Time Stamp 25 SEP 2020 20:12

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:52

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 SEP 2020 17:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 22:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 9

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 20:06

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 09:57

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**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

22 SEP 2020 13:56

PC Open Date & Time

22 SEP 2020 13:49

PC Close Date & Time

22 SEP 2020 16:19

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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

23

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

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 21:17

PC Open Date & Time

22 SEP 2020 17:14

PC Close Date & Time

23 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

780

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 09:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 20:13

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 20:52

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 17:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**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 ☐

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 13:57
PC Open Date & Time	22 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 16:19

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**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 ☐

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 21:19
PC Open Date & Time	22 SEP 2020 17:14
PC Close Date & Time	23 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

110 of 3359

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 09:11
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

112 of 3359

EAB) (1725)

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:40
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

114 of 3359

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:14
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

116 of 3359

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:53
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

118 of 3359

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

120 of 3359

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:31
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

30 SEP 2020 20:06

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

---

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

02 OCT 2020 09:57

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

---

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 OCT 2020 16:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

---

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

---

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 29 SEP 2020 22:11

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 SEP 2020 20:06

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 09:57

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp 02 OCT 2020 16:04

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 29 SEP 2020 22:11

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 29 SEP 2020 22:12

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59



US3392112

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 17:24:17

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity ☐  
not requiring medical attention

Prevents daily activity and ☐  
requires medical attention

---

PC Open Date & Time	29 SEP 2020 12:00
---------------------	-------------------

PC Close Date & Time	30 SEP 2020 11:59
----------------------	-------------------

PC Time stamp	29 SEP 2020 22:12
---------------	-------------------

---

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 22:12
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 20:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 09:58
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 16:04
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3392112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:55:39

Generated On: 09 Jun 2021 17:24:17

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*



US3392112

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:55:39

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:39:25

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:39:25

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:22:04

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:22:04

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:21:41

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:21:41

Generated On: 09 Jun 2021 17:24:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:37
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3392112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:21:41

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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



US3392112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:21:41

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

12:50 (24 HR)

Collection date and time (derived)

19 OCT 2020 12:50

US3392112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:21:41

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59



US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 NOV 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 11:59:59
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 12:11:12

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 18:04:35
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 00:02:37
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 DEC 2020 12:08:25
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 JAN 2021 00:08:23
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59



US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 11:49:12

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 16:33:33

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 JAN 2021 15:11:17
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

---

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 12:00:00

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59



US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 187

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAR 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 12:22:17

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:02:55

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 APR 2021 01:07:16
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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°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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 12:15:02

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:04:12

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 MAY 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 MAY 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 JUN 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 JUN 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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°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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 JUL 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 AUG 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

15 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

19 AUG 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 SEP 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	03 OCT 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59
---	-------------------

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 NOV 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
---	-------------------

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 NOV 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 DEC 2021 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
---	-------------------

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 FEB 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 FEB 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 MAR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 APR 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 MAY 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 JUN 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 JUN 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JUL 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JUL 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 JUL 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 AUG 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 AUG 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 SEP 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 SEP 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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

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 ☐

**US3392112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 SEP 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 SEP 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 SEP 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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°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 ☐

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 OCT 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

---

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**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 ☐



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3392112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:24:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		18 MAR 2021 12:22:48

US3392112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:55:34

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:55:34

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3392112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392112

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

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) \_\_\_\_\_



US3392112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

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.*

US3392112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 MAR 2021

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

8 MAR 2021 14:05

US3392112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:05:48

Generated On: 09 Jun 2021 17:24:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3392112**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

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*

**US3392112**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Date of Contact	18 NOV 2020
Time of Contact	14:32
Date and Time of Contact (derived)	18 NOV 2020 14:32
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Date of Visit	18 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Date of Visit	19 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	19 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

373 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

381 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

397 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

401 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

405 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

409 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

413 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

417 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

421 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

425 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

426 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

429 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

433 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

437 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

441 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

445 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

449 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Date of Visit 09 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 09 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☐ Nasal Swab ☐ Saliva Test ☒ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

453 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

454 of 3359

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date



US3392112

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 OCT 2020
Day 5	Yes	22 OCT 2020
Day 7	Yes	25 OCT 2020
Day 9	Yes	27 OCT 2020
Day 14	Yes	01 NOV 2020
Day 21	Yes	09 NOV 2020
Day 28	NA (COVID-19 Negative)	

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 20:05:44

Generated On: 09 Jun 2021 17:24:17

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:37
Height (xxx.x)	58.0 in
Weight (xxx.x)	169.0 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

19 OCT 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 14:40
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

18 NOV 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID SICKD28

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

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) \_\_\_\_\_

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

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.*

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 14 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

12:18 (24 HR)

Collection date and time (derived)

14 JAN 2021 12:18

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 20:05:45

Generated On: 09 Jun 2021 17:24:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	14 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	12:12
---------------------------------	-------

Collection Date and Time (derived)	14 JAN 2021 12:12
------------------------------------	-------------------

US3392112

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

AEID	USA-US119-2020-MRNA-1273-P30 1000014
Adverse event	SMALL BOWEL OBSTRUCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	30 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

475 of 3359

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	SUBJECT WAS ADMITTED TO HOSPITAL WITH SMALL BOWEL OBSTRUCTION. DESCRIBES THE PAIN IS A CRAMPY SENSATION IN HER LEFT LOWER QUADRANT REGION.

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 29 Apr 2021 20:05:42

**Generated On: 09 Jun 2021 17:24:17**

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

AEID

Adverse event

MUSCLE ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 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)

02 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

478 of 3359

EAB) (1725)

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	



US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

480 of 3359

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

AEID	USA-US119-2021-MRNA-1273-P30 1000010
Adverse event	ACUTE KIDNEY INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	01 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

482 of 3359

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS ADMITTED TO ED AND RECEIVED IV FLUIDS FOR ACUTE KIDNEY INJURY. MEDICAL RECORDS WERE SENT TO SPONSOR ON 09MAR2021.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003  
EAB) (1725)

483 of 3359

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed:** (b) (4) 29 Apr 2021 20:05:42

**Generated On: 09 Jun 2021 17:24:17**

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 800

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)

486 of 3359

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE,  
HEADACHE

Dose per administration 800

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

488 of 3359

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE,  
HEADACHE

Dose per administration 800

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

490 of 3359

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication HERPES SIMPLEX

Dose per administration 800

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

492 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 1951	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication POTASSIUM CL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify MEQ

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

494 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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

496 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

498 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR BACK PAIN

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

500 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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 AUG 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication PREGABALIN

Prophylaxis Yes ☐  
No ☒

Indication FIBROMYALGIA

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

502 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

504 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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 AUG 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

506 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 1982	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication VITAMIN D2

Prophylaxis Yes ☐  
No ☒

Indication ANEMIA

Dose per administration 50000

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

508 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication KNEE PAIN

Dose per administration 800

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

510 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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 AUG 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication TORADOL

Prophylaxis Yes ☐  
No ☒

Indication KNEE PAIN

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

512 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication METOCLOPRAMIDE HCL

Prophylaxis Yes ☐  
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☒  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

514 of 3359

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	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)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication ZOFRAN [ODANSETRON]

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, SECONDARY TO  
SMALL BOWEL OBSTRUCTION

Dose per administration 4

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

516 of 3359

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

Name of Medication 0.9% NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 500

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

518 of 3359

EAB) (1725)

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 20:05:42

Generated On: 09 Jun 2021 17:24:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3392112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:05:43

Generated On: 09 Jun 2021 17:24:17

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3392112

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:24:17

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

US3392112

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:24:17

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 ☐

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
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)	20/NOV/2020 11:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
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)	07/DEC/2020 06:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000014
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000014
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/DEC/2020 15:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000014
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/JAN/2021 10:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 20:05:47

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2020-MRNA-1273-P301000014
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/MAR/2021 07:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 17:10:28

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2021-MRNA-1273-P301000010
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 17:10:28

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2021-MRNA-1273-P301000010
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	MICHAEL
Investigator's Last Name	COTUGNO
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)	21/APR/2021 11:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 17:10:28

Generated On: 09 Jun 2021 17:24:17

SAEID	USA-US119-2021-MRNA-1273-P301000010
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	MICHAEL
Investigator's Last Name	COTUGNO
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)	29/APR/2021 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3392112 (Prod: Benchmark Research - Metairie - PPDS)

**US3392112**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:24:17**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:26:29
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:26:24
User entered 'US3392112'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:39:22

US3392112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 20:35:53



US3392112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:39:24

US3392112

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[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 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	28 Aug 2020 20:35:53

**US3392112**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'SCRN'	System	28 Aug 2020 20:35:53

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:39:25

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '72'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'YEARS'	System	28 Aug 2020 20:37:07

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '72'	System	28 Aug 2020 20:37:56

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Female (F)'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07



US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'I'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07



**US3392112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:24:17**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:07

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:56

**US3392112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:24:17**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Aug 2020'	System	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2020'	System	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:47:14
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	21 Sep 2020 21:11:09
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	21 Sep 2020 21:11:03
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:02:44
User entered 'Amendment 5 (5)'	Brenda Lawson (b) (4) (b) (4)	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 20:37:56



US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	Brenda Lawson (b) (4)	28 Aug 2020 20:37:56

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:39:24

US3392112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'I'	System	28 Aug 2020 20:38:05

US3392112

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:24:17

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 20:38:05

US3392112

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:24:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:55:15
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:56:45
Data point term sent to Coder	System	31 Aug 2020 22:55:55
User entered 'anemia'	Brandon Illickal (b) (4)	31 Aug 2020 22:55:33

US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Jul 2018'	(b) (4)	31 Aug 2020 22:55:33
	Brandon Illickal (b) (4)	



US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:55:33

**US3392112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:55:33
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:55:33

US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:55:33

**US3392112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Jul 2018'	System	31 Aug 2020 22:55:33

**US3392112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2018'	System	31 Aug 2020 22:55:33

US3392112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:55:33

**US3392112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:55:33



US3392112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:57:46
Data point term sent to Coder	System	31 Aug 2020 22:56:58
User entered 'herpes simplex'	Brandon Illickal (b) (4)	31 Aug 2020 22:56:00

US3392112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Mar 1951'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:56:00

US3392112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:00

**US3392112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:56:00
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:56:00
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:00
	Brandon Illickal (b) (4)	

**US3392112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Mar 1951'	System	31 Aug 2020 22:56:00

**US3392112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '1951'	System	31 Aug 2020 22:56:00



**US3392112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:00

**US3392112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:00

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
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)	31 Aug 2020 22:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:57:46
Data point term sent to Coder	System	31 Aug 2020 22:56:59
User entered 'post-menopausal'	Brandon Illickal (b) (4)	31 Aug 2020 22:56:30

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un May 2005'	(b) (4)	31 Aug 2020 22:56:30
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:30

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:56:30
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:56:30

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:30



**US3392112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'May 2005'	System	31 Aug 2020 22:56:30

**US3392112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2005'	System	31 Aug 2020 22:56:30

US3392112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:30

**US3392112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:30

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Per CDM: Please consider adding missing concomitant medication for this condition or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 07:51:13
Query 'Per CDM: Please consider adding missing concomitant medication for this condition or clarify otherwise. Thank you!' answered with 'HYPERTENSION MEDS ADDED IN EDC' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:38:47
User opened query 'Per CDM: Please consider adding missing concomitant medication for this condition or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:12:53
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	21 Oct 2020 11:11:53
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	20 Oct 2020 21:30:13
' answered with 'DATA ENTERED' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	06 Oct 2020 08:18:14
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:58:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:58:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

596 of 3359

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	31 Aug 2020 22:58:00
User entered 'hypertension'	Brandon Illickal (b) (4)	31 Aug 2020 22:56:59

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Jan 2010'	(b) (4)	31 Aug 2020 22:56:59

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:59



US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:56:59
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:56:59

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:56:59

US3392112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Jan 2010'	System	31 Aug 2020 22:56:59

**US3392112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2010'	System	31 Aug 2020 22:56:59

**US3392112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:59

**US3392112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:56:59

US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:58:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:58:36
Data point term sent to Coder	System	31 Aug 2020 22:57:59
User entered 'back pain'	Brandon Illickal (b) (4)	31 Aug 2020 22:57:23



US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Aug 2017'	(b) (4)	31 Aug 2020 22:57:23

US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:57:23

US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:57:23
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:57:23
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:57:23

**US3392112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Aug 2017'	System	31 Aug 2020 22:57:23

**US3392112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2017'	System	31 Aug 2020 22:57:23

**US3392112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:57:23



**US3392112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:57:23

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:58:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:58:36
Data point term sent to Coder	System	31 Aug 2020 22:58:00
User entered 'fibromyalgia'	Brandon Illickal (b) (4)	31 Aug 2020 22:57:40

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Jul 2019'	(b) (4)	31 Aug 2020 22:57:40

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:57:40

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:57:40
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:57:40

US3392112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:57:40

**US3392112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Jul 2019'	System	31 Aug 2020 22:57:40



**US3392112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2019'	System	31 Aug 2020 22:57:40

**US3392112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:57:40

**US3392112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	31 Aug 2020 22:57:40

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 23:22:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 23:22:59
Data point term sent to Coder	System	14 Jan 2021 23:22:11
User entered 'lumbar back pain'	Brandon Illickal (b) (4)	14 Jan 2021 23:21:25

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Aug 2017'	(b) (4)	14 Jan 2021 23:21:25

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Jan 2021 23:21:25

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	14 Jan 2021 23:21:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	14 Jan 2021 23:21:25
	Brandon Illickal (b) (4)	



US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Jan 2021 23:21:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Aug 2017'	System	14 Jan 2021 23:21:25

**US3392112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2017'	System	14 Jan 2021 23:21:25

US3392112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Jan 2021 23:21:25

**US3392112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Jan 2021 23:21:25

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Jan 2021 23:25:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 23:25:59
Data point term sent to Coder	System	14 Jan 2021 23:25:14
User entered 'acid reflux'	Brandon Illickal (b) (4)	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Aug 2015'	(b) (4)	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Jan 2021 23:24:36



US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	14 Jan 2021 23:24:36
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Aug 2015'	System	14 Jan 2021 23:24:36

**US3392112**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2015'	System	14 Jan 2021 23:24:36

**US3392112**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Jan 2021 23:24:36

US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Feb 2021 01:14:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Feb 2021 01:14:51
Data point term sent to Coder	System	14 Feb 2021 01:14:13
User entered 'knee pain'	Brandon Illickal (b) (4)	14 Feb 2021 01:13:30



US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un Aug 2005'	(b) (4)	14 Feb 2021 01:13:30

US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Feb 2021 01:13:30

US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	14 Feb 2021 01:13:30
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	14 Feb 2021 01:13:30

US3392112

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	14 Feb 2021 01:13:30

**US3392112**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'Aug 2005'	System	14 Feb 2021 01:13:30

**US3392112**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '2005'	System	14 Feb 2021 01:13:30

**US3392112**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Feb 2021 01:13:30



**US3392112**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered empty.	System	14 Feb 2021 01:13:30

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '14:42' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

**US3392112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '28 Aug 2020 14:42'	System	31 Aug 2020 22:53:18
User entered empty.	System	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '58.0' in reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:38:05

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 22:54:31
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:54:31
User entered '168.9' lb reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:54:31
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:38:05

**US3392112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered '35.37395'	System	31 Aug 2020 22:54:31
User entered empty.	System	28 Aug 2020 21:10:37
DataPoint set to visible.	System	28 Aug 2020 20:38:05



US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'kg/m2'	System	31 Aug 2020 22:54:31
User entered empty.	System	28 Aug 2020 21:10:37
DataPoint set to visible.	System	28 Aug 2020 20:38:05

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:20
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 18:04:38
User entered missing code ND - Not Done; reason for change Per Query Resolution	Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:17:10
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '98.1' F reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '72' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

**US3392112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'bpm'	System	31 Aug 2020 22:53:18
User entered empty.	System	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '14' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'breaths/min'	System	31 Aug 2020 22:53:18
User entered empty.	System	28 Aug 2020 21:10:37



US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '108' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'mmHg'	System	31 Aug 2020 22:53:18
User entered empty.	System	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:04:32
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 22:53:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 22:53:18
User entered '64' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:53:18
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:10:37
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User entered 'mmHg'	System	31 Aug 2020 22:53:18
User entered empty.	System	28 Aug 2020 21:10:37

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12

US3392112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12

US3392112

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 22:57:47
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	01 Sep 2020 15:22:03
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	01 Sep 2020 15:22:03
User entered '28 Aug 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Sep 2020 15:22:03
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	31 Aug 2020 23:01:03
User entered '31 Aug 2020'	Brandon Illickal (b) (4)	31 Aug 2020 22:57:47



US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4) System	31 Aug 2020 22:59:47
User entered '28 Aug 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	31 Aug 2020 22:59:47
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	31 Aug 2020 22:58:29
User entered '31 Aug 2020'	Brandon Illickal (b) (4)	31 Aug 2020 22:58:29

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 22:58:29
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:58:29

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:58:29

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 22:58:29
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:58:29

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'un May 2005'	(b) (4)	31 Aug 2020 22:58:29
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:17

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 22:58:29



US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:00:50



US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'No (N)'	Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'retired'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

**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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	Brandon Illickal (b) (4)	31 Aug 2020 23:00:50



US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

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)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered 'I'	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered '0'	(b) (4)	31 Aug 2020 23:00:50

US3392112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:20:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:15
User entered empty.	(b) (4)	31 Aug 2020 23:00:50
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:01:03
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:01:03

US3392112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Clinic (Clinic)'	(b) (4)	31 Aug 2020 23:01:03
	Brandon Illickal (b) (4)	



**US3392112**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'VISIT1'	System	31 Aug 2020 23:01:03

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:34

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '188957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:34

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:34

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

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)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:03:10

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

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)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:03:10

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:03:10
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:03:10



US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'No (N)'	(b) (4)	31 Aug 2020 23:03:10
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:17

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:32:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:32:57

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:17
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:07:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:17:19
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:17
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:07:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:17:19
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	



US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '14:42'	(b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered '28 Aug 2020 14:42'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '98.1' F	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Oral (Oral)'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered empty.	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '72'	(b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'bpm'	System	31 Aug 2020 23:04:54



US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '14'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'breaths/min'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '108'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'mmHg'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '64'	(b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'mmHg'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:17
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:07:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:17:19
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:07:45
User entered empty.	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54



US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '16:11'	(b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered '28 Aug 2020 16:11'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '98.2' F	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Oral (Oral)'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered empty.	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	



US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '68'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'bpm'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '16'	(b) (4)	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'breaths/min'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '102'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'mmHg'	System	31 Aug 2020 23:04:54

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '70'	(b) (4)	31 Aug 2020 23:04:54
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'mmHg'	System	31 Aug 2020 23:04:54



US3392112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:03:19
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	(b) (4)	31 Aug 2020 23:03:19
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

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)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '15:40'	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19



**US3392112**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:24:17**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered '28 Aug 2020 15:40'	System	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'ONCE'	System	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:11:19

US3392112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 21:13:59

US3392112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	28 Aug 2020 21:13:59

US3392112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '15:15'	Brenda Lawson (b) (4)	28 Aug 2020 21:13:59

**US3392112**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered '28 Aug 2020 15:15'	System	28 Aug 2020 21:13:59



US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4) (b) (4)	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered '15:10'	Brenda Lawson (b) (4)	28 Aug 2020 21:14:18

**US3392112**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered '28 Aug 2020 15:10'	System	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4) (b) (4)	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
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	01 Sep 2020 14:58:05
User entered 'No (N)' reason for change: Per Query Resolution	System	01 Sep 2020 14:58:05
User opened query 'Data is required. Please complete.' (Site from System).	Brandon Illickal (b) (4)	01 Sep 2020 14:58:05
User entered empty.	(b) (4)	
	System	28 Aug 2020 21:14:18
	Brenda Lawson (b) (4)	28 Aug 2020 21:14:18
	(b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered empty.	Brenda Lawson (b) (4)	28 Aug 2020 21:14:18



US3392112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered empty.	System	28 Aug 2020 21:14:18

US3392112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:21
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 23:03:23
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'I'	System	31 Aug 2020 23:03:23

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:17:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '0bd3a977-f4fb-4865-ab03-cf11543a6048' User entered 'Yes (Y)'	System	28 Aug 2020 21:18:02
	System	28 Aug 2020 21:18:02

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:17:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '0bd3a977-f4fb-4865-ab03-cf11543a6048' User entered '98.2'	System	28 Aug 2020 21:18:02
	System	28 Aug 2020 21:18:02

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:17:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '0bd3a977-f4fb-4865-ab03-cf11543a6048'	System	28 Aug 2020 21:18:02
User entered 'No (N)'	System	28 Aug 2020 21:18:02

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:17:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '0bd3a977-f4fb-4865-ab03-cf11543a6048' User entered '28 Aug 2020 16:17'	System	28 Aug 2020 21:18:02
	System	28 Aug 2020 21:18:02



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 16:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 18:30'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:46:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2e2f893a-21a8-4906-8c9e-5ba5c8d79b0d' User entered 'Yes (Y)'	System	29 Aug 2020 15:48:22
	System	29 Aug 2020 15:48:22

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:46:21', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2e2f893a-21a8-4906-8c9e-5ba5c8d79b0d' User entered '97.4'	System	29 Aug 2020 15:48:22
	System	29 Aug 2020 15:48:22

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:46:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2e2f893a-21a8-4906-8c9e-5ba5c8d79b0d' User entered 'No (N)'	System	29 Aug 2020 15:48:22
	System	29 Aug 2020 15:48:22

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:48:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2e2f893a-21a8-4906-8c9e-5ba5c8d79b0d' User entered '29 Aug 2020 10:48'	System	29 Aug 2020 15:48:22
	System	29 Aug 2020 15:48:22

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 19:25'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 2'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:01:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e' User entered 'Yes (Y)'	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:01:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e' User entered '96.5'	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:01:55', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e'	System	29 Aug 2020 17:02:16
User entered 'Yes (Y)'	System	29 Aug 2020 17:02:16

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:02:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:02:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e' User entered '1'	Brandon Illickal (b) (4)	30 Sep 2020 18:30:34
	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:02:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e' User entered '0'	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:02:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '96578f0d-c67c-4344-b752-4a4e17167b6e' User entered '29 Aug 2020 12:02'	System	29 Aug 2020 17:02:16
	System	29 Aug 2020 17:02:16



**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 3'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:55:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '253cdfef-f2f7-4454-9016-612f059dac6e' User entered 'Yes (Y)'	System	31 Aug 2020 15:57:48
	System	31 Aug 2020 15:57:48

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:01', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '253cdfce-f2f7-4454-9016-612f059dac6e' User entered '98.0'	System	31 Aug 2020 15:57:48
	System	31 Aug 2020 15:57:48

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '253cdfef-f2f7-4454-9016-612f059dac6e'	System	31 Aug 2020 15:57:48
User entered 'No (N)'	System	31 Aug 2020 15:57:48

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '253cdfee-f2f7-4454-9016-612f059dac6e' User entered '31 Aug 2020 10:56'	System	31 Aug 2020 15:57:48
	System	31 Aug 2020 15:57:48

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 4'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:02:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8' User entered 'Yes (Y)'	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:02:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8' User entered '98.1'	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8'	System	01 Sep 2020 16:03:54
User entered 'Yes (Y)'	System	01 Sep 2020 16:03:54

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:02:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8' User entered '1'	Brandon Illickal (b) (4)	30 Sep 2020 18:32:08
	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8' User entered '0'	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:14', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '813d8c14-0d76-4935-bc90-e98dbda6d5f8' User entered '01 Sep 2020 11:03'	System	01 Sep 2020 16:03:54
	System	01 Sep 2020 16:03:54



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 5'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 6'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:44:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e' User entered 'Yes (Y)'	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:05', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e' User entered '98.1'	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:16', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e'	System	02 Sep 2020 19:45:36
User entered 'Yes (Y)'	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:02:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e' User entered '1'	Brandon Illickal (b) (4)	30 Sep 2020 18:33:19
	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e' User entered '0'	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'acd831dd-8eb3-4fc5-9091-d6dd075d439e' User entered '02 Sep 2020 14:45'	System	02 Sep 2020 19:45:36
	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 7'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:50:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'd747955a-e2c4-4a2a-91c9-0b5a78be3616' User entered 'Yes (Y)'	System	03 Sep 2020 18:56:08
	System	03 Sep 2020 18:56:08

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:55:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'd747955a-e2c4-4a2a-91c9-0b5a78be3616' User entered '97.4'	System	03 Sep 2020 18:56:08
	System	03 Sep 2020 18:56:08

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:01', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'd747955a-e2c4-4a2a-91c9-0b5a78be3616' User entered 'No (N)'	System	03 Sep 2020 18:56:08
	System	03 Sep 2020 18:56:08



US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'd747955a-e2c4-4a2a-91c9-0b5a78be3616' User entered '03 Sep 2020 13:56'	System	03 Sep 2020 18:56:08
	System	03 Sep 2020 18:56:08

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:07', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '905460fd-493f-41b7-9a87-3b370f380132'	System	28 Aug 2020 21:18:35
User entered 'None (1)'	System	28 Aug 2020 21:18:35

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '905460fd-493f-41b7-9a87-3b370f380132' User entered 'No (N)'	System	28 Aug 2020 21:18:35
	System	28 Aug 2020 21:18:35

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '905460fd-493f-41b7-9a87-3b370f380132' User entered 'No (N)'	System	28 Aug 2020 21:18:35
	System	28 Aug 2020 21:18:35

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '905460fd-493f-41b7-9a87-3b370f380132' User entered 'None (1)'	System	28 Aug 2020 21:18:35
	System	28 Aug 2020 21:18:35



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '905460fd-493f-41b7-9a87-3b370f380132' User entered '28 Aug 2020 16:18'	System	28 Aug 2020 21:18:35
	System	28 Aug 2020 21:18:35

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 16:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 18:30'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:50:02', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:50:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered 'No (N)'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:51:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered 'Yes (Y)'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:53:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered '63'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:53:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered 'None (1)'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:54:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1b2e7e81-f716-4ea2-9b9b-8b1499d33d2f' User entered '29 Aug 2020 10:54'	System	29 Aug 2020 15:54:33
	System	29 Aug 2020 15:54:33

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Aug 2020 19:25'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 2'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:03:39', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e'	System	29 Aug 2020 17:04:47
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	29 Aug 2020 17:04:47

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:03:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e' User entered 'No (N)'	System	29 Aug 2020 17:04:47
	System	29 Aug 2020 17:04:47

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:03:48', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e' User entered 'Yes (Y)'	System	29 Aug 2020 17:04:47
	System	29 Aug 2020 17:04:47



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:04:22', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e' User entered '64'	System	29 Aug 2020 17:04:47
	System	29 Aug 2020 17:04:47

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:04:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e' User entered 'None (1)'	System	29 Aug 2020 17:04:47
	System	29 Aug 2020 17:04:47

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:04:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '570dd981-b1c8-4124-8ca1-465f3cca644e' User entered '29 Aug 2020 12:04'	System	29 Aug 2020 17:04:47
	System	29 Aug 2020 17:04:47

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 3'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc'	System	31 Aug 2020 15:58:09
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 15:58:09

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc' User entered 'No (N)'	System	31 Aug 2020 15:58:09
	System	31 Aug 2020 15:58:09



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:56:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc' User entered 'Yes (Y)'	System	31 Aug 2020 15:58:09
	System	31 Aug 2020 15:58:09

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc' User entered '50'	System	31 Aug 2020 15:58:09
	System	31 Aug 2020 15:58:09

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:07', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc' User entered 'None (1)'	System	31 Aug 2020 15:58:09
	System	31 Aug 2020 15:58:09

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'beab6e52-b18d-4aca-8904-e85bb52e59bc' User entered '31 Aug 2020 10:57'	System	31 Aug 2020 15:58:09
	System	31 Aug 2020 15:58:09

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 4'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6ff1673-adb1-454c-9232-82773a9325a1'	System	01 Sep 2020 16:04:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Sep 2020 16:04:21



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6ff1673-adb1-454c-9232-82773a9325a1' User entered 'No (N)'	System	01 Sep 2020 16:04:21
	System	01 Sep 2020 16:04:21

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6ff1673-adb1-454c-9232-82773a9325a1' User entered 'No (N)'	System	01 Sep 2020 16:04:21
	System	01 Sep 2020 16:04:21

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:03:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6ff1673-adb1-454c-9232-82773a9325a1' User entered 'None (1)'	System	01 Sep 2020 16:04:21
	System	01 Sep 2020 16:04:21

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:04:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6ff1673-adb1-454c-9232-82773a9325a1' User entered '01 Sep 2020 11:04'	System	01 Sep 2020 16:04:21
	System	01 Sep 2020 16:04:21

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 5'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 6'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebdfc47d-f632-4b5c-b0f9-d7161c0fb559'	System	02 Sep 2020 19:46:07
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 19:46:07

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebdfc47d-f632-4b5c-b0f9-d7161c0fb559' User entered 'No (N)'	System	02 Sep 2020 19:46:07
	System	02 Sep 2020 19:46:07

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebdfc47d-f632-4b5c-b0f9-d7161c0fb559'	System	02 Sep 2020 19:46:07
User entered 'No (N)'	System	02 Sep 2020 19:46:07

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:45:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebdfc47d-f632-4b5c-b0f9-d7161c0fb559'	System	02 Sep 2020 19:46:07
User entered 'None (1)'	System	02 Sep 2020 19:46:07

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebdfc47d-f632-4b5c-b0f9-d7161c0fb559'	System	02 Sep 2020 19:46:07
User entered '02 Sep 2020 14:46'	System	02 Sep 2020 19:46:07

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 7'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '879a83b8-707d-4108-84cd-20b0c62159d6'	System	03 Sep 2020 18:56:29
User entered 'None (1)'	System	03 Sep 2020 18:56:29

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:16', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '879a83b8-707d-4108-84cd-20b0c62159d6'	System	03 Sep 2020 18:56:29
User entered 'No (N)'	System	03 Sep 2020 18:56:29

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '879a83b8-707d-4108-84cd-20b0c62159d6'	System	03 Sep 2020 18:56:29
User entered 'No (N)'	System	03 Sep 2020 18:56:29

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '879a83b8-707d-4108-84cd-20b0c62159d6'	System	03 Sep 2020 18:56:29
User entered 'None (1)'	System	03 Sep 2020 18:56:29

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '879a83b8-707d-4108-84cd-20b0c62159d6'	System	03 Sep 2020 18:56:29
User entered '03 Sep 2020 13:56'	System	03 Sep 2020 18:56:29

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:18:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:19:05', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:19:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:19:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'None (0)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:19:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered 'No (N)'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-28T16:19:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '65ba14a2-c615-4b6e-bd48-3e038324daac' User entered '28 Aug 2020 16:19'	System	28 Aug 2020 21:19:38
	System	28 Aug 2020 21:19:38

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '28 Aug 2020 16:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '28 Aug 2020 18:30'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871'	System	29 Aug 2020 15:56:10
User entered 'No interference with activity (1)'	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871'	System	29 Aug 2020 15:56:10
User entered 'No interference with activity (1)'	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered 'None (0)'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered 'None (0)'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered 'None (0)'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered 'None (0)'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:55:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered 'No (N)'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T10:56:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a7983257-0494-47a8-bc43-e7a43cf8d871' User entered '29 Aug 2020 10:56'	System	29 Aug 2020 15:56:10
	System	29 Aug 2020 15:56:10

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '28 Aug 2020 19:25'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 2'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:04:58', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932'	System	29 Aug 2020 17:06:13
User entered 'No interference with activity (1)'	System	29 Aug 2020 17:06:13



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:05:09', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932' User entered 'None (0)'	System	29 Aug 2020 17:06:13
	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:05:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932'	System	29 Aug 2020 17:06:13
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:05:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932'	System	29 Aug 2020 17:06:13
User entered 'No interference with activity (1)'	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:05:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932' User entered 'None (0)'	System	29 Aug 2020 17:06:13
	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:05:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932' User entered 'None (0)'	System	29 Aug 2020 17:06:13
	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:06:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932'	System	29 Aug 2020 17:06:13
User entered 'No (N)'	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-29T12:06:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8edf6763-3117-4aa7-9088-f6b329b90932' User entered '29 Aug 2020 12:06'	System	29 Aug 2020 17:06:13
	System	29 Aug 2020 17:06:13

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 3'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:37:58
Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	03 Mar 2021 00:34:48
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:49:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a'	System	31 Aug 2020 15:58:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a'	System	31 Aug 2020 15:58:58
User entered 'No interference with activity (1)'	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a'	System	31 Aug 2020 15:58:58
User entered 'No interference with activity (1)'	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:57:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a'	System	31 Aug 2020 15:58:58
User entered 'No interference with activity (1)'	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:58:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a' User entered 'None (0)'	System	31 Aug 2020 15:58:58
	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:58:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a' User entered 'None (0)'	System	31 Aug 2020 15:58:58
	System	31 Aug 2020 15:58:58



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:58:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a' User entered 'No (N)'	System	31 Aug 2020 15:58:58
	System	31 Aug 2020 15:58:58

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-08-31T10:58:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '723c4732-830f-47b2-b390-15c4f296313a' User entered '31 Aug 2020 10:58'	System	31 Aug 2020 15:58:58
	System	31 Aug 2020 15:58:58

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 4'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:04:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0'	System	01 Sep 2020 16:05:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:04:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0'	System	01 Sep 2020 16:05:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:04:33', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0'	System	01 Sep 2020 16:05:52
User entered 'Some interference with activity (2)'	System	01 Sep 2020 16:05:52



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:04:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0'	System	01 Sep 2020 16:05:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:05:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0' User entered 'None (0)'	System	01 Sep 2020 16:05:52
	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:05:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0' User entered 'None (0)'	System	01 Sep 2020 16:05:52
	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:05:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0' User entered 'No (N)'	System	01 Sep 2020 16:05:52
	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-01T11:05:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e387b5a1-e591-4367-8a73-81df059fc3f0' User entered '01 Sep 2020 11:05'	System	01 Sep 2020 16:05:52
	System	01 Sep 2020 16:05:52

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 5'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:24:17**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12



**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 6'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2'	System	02 Sep 2020 19:47:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2'	System	02 Sep 2020 19:47:10
User entered 'Significant; prevents daily activity (3)'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2'	System	02 Sep 2020 19:47:10
User entered 'Some interference with activity (2)'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2'	System	02 Sep 2020 19:47:10
User entered 'Some interference with activity (2)'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:48', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2' User entered 'None (0)'	System	02 Sep 2020 19:47:10
	System	02 Sep 2020 19:47:10



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:46:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2' User entered 'None (0)'	System	02 Sep 2020 19:47:10
	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:47:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2' User entered 'No (N)'	System	02 Sep 2020 19:47:10
	System	02 Sep 2020 19:47:10

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-02T14:47:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4c855b8-5d83-4b84-9dc8-4917c9c655d2' User entered '02 Sep 2020 14:47'	System	02 Sep 2020 19:47:10
	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 7'	System	28 Aug 2020 21:11:19

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:33', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered 'None (0)'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523'	System	03 Sep 2020 18:57:30
User entered 'Some interference with activity (2)'	System	03 Sep 2020 18:57:30



US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:56:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered 'None (0)'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:57:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered 'None (0)'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:57:07', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered 'None (0)'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:57:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered 'None (0)'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

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)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:57:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523'	System	03 Sep 2020 18:57:30
User entered 'Yes (Y)'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-03T13:57:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '27a5e61f-d296-4dc5-bd76-4d4e1b53e523' User entered '03 Sep 2020 13:57'	System	03 Sep 2020 18:57:30
	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:11:19



US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Sep 2020 19:47:10
User entered 'Day 8'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-04T18:18:45', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3017d38c-b349-41dc-b3cd-e20e8614aa9a'	System	04 Sep 2020 23:18:51
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:18:51

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-04T18:18:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3017d38c-b349-41dc-b3cd-e20e8614aa9a'	System	04 Sep 2020 23:18:51
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 23:18:51

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:47:10

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:47:10

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	03 Sep 2020 18:57:30
User entered 'Day 9'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19



**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	04 Sep 2020 23:18:51
User entered 'Day 10'	System	04 Sep 2020 23:18:51

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-06T14:17:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c691d322-a8ef-4840-92ce-8621f134b753'	System	06 Sep 2020 19:17:23
User entered 'No interference with activity (1)'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-06T14:17:21', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c691d322-a8ef-4840-92ce-8621f134b753' User entered '06 Sep 2020 14:17'	System	06 Sep 2020 19:17:23
	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:18:51

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:18:51

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	06 Sep 2020 19:17:23
User entered 'Day 11'	System	06 Sep 2020 19:17:23



US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-07T12:00:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '80c0bff3-3706-4748-a152-068e504ae7c6'	System	07 Sep 2020 17:00:37
User entered 'No interference with activity (1)'	System	07 Sep 2020 17:00:37

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-07T12:00:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '80c0bff3-3706-4748-a152-068e504ae7c6' User entered '07 Sep 2020 12:00'	System	07 Sep 2020 17:00:37
	System	07 Sep 2020 17:00:37

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	06 Sep 2020 19:17:23
User entered 'Day 12'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-09T09:58:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ca6c66fc-8d14-4566-8d2d-cd85abeef88c' User entered 'None (0)'	System	09 Sep 2020 14:58:35
	System	09 Sep 2020 14:58:35

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-09T09:58:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ca6c66fc-8d14-4566-8d2d-cd85abeef88c' User entered '09 Sep 2020 09:58'	System	09 Sep 2020 14:58:35
	System	09 Sep 2020 14:58:35

US3392112

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 19:17:23



**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Sep 2020 19:45:36
User entered 'Day 8'	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-04T18:18:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'eca42186-b63b-4f83-b114-8eda0d83a3ef' User entered 'No (N)'	System	04 Sep 2020 23:19:04
	System	04 Sep 2020 23:19:04

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-04T18:19:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'eca42186-b63b-4f83-b114-8eda0d83a3ef' User entered '04 Sep 2020 18:19'	System	04 Sep 2020 23:19:04
	System	04 Sep 2020 23:19:04

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:45:36

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	03 Sep 2020 18:57:30
User entered 'Day 9'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19



US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:57:30

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	04 Sep 2020 23:18:51
User entered 'Day 10'	System	04 Sep 2020 23:18:51

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-06T14:17:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a03b67c3-3aa3-4df9-8060-2b70fa0d7385' User entered 'No (N)'	System	06 Sep 2020 19:17:34
	System	06 Sep 2020 19:17:34

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-06T14:17:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a03b67c3-3aa3-4df9-8060-2b70fa0d7385' User entered '06 Sep 2020 14:17'	System	06 Sep 2020 19:17:34
	System	06 Sep 2020 19:17:34

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:18:51

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:18:51



US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	06 Sep 2020 19:17:23
User entered 'Day 11'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-07T12:00:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '84f689d4-65fc-454a-ac84-b996f15796af' User entered 'No (N)'	System	07 Sep 2020 17:00:53
	System	07 Sep 2020 17:00:53

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-07T12:00:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '84f689d4-65fc-454a-ac84-b996f15796af' User entered '07 Sep 2020 12:00'	System	07 Sep 2020 17:00:53
	System	07 Sep 2020 17:00:53

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 19:17:23

**US3392112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	06 Sep 2020 19:17:23
User entered 'Day 12'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-09T09:58:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '84026d59-e91d-42c7-9eee-cf0d8ce1a711' User entered 'No (N)'	System	09 Sep 2020 14:58:41
	System	09 Sep 2020 14:58:41

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-09T09:58:39', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '84026d59-e91d-42c7-9eee-cf0d8ce1a711' User entered '09 Sep 2020 09:58'	System	09 Sep 2020 14:58:41
	System	09 Sep 2020 14:58:41



US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 19:17:23

US3392112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 19:17:23

US3392112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 13:16:39

US3392112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:02
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	11 Sep 2020 13:18:14
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	11 Sep 2020 13:18:14
User entered '5 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 13:18:14
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 13:16:39
User entered '3 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 13:16:39

US3392112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:16:39

US3392112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:02
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:16:39

US3392112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 13:18:19

US3392112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:26
User entered 'I'	System	11 Sep 2020 13:18:19



**US3392112**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 13:19:14

US3392112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:31:32
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:19:14

US3392112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:31:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:19:14

US3392112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:31:32
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:19:14

US3392112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 13:19:20

**US3392112**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:24
User entered 'I'	System	11 Sep 2020 13:19:20

**US3392112**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:22:26

US3392112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:04
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:22:26



US3392112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:22:26

**US3392112**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:04
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:22:26

US3392112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:22:32

US3392112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	18 Sep 2020 21:22:32

US3392112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User closed query 'Per GCL Lab Reconciliation Re-query: SWAB: COVID diagnostic test swab sample collected on 19Oct2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:20:26
Query 'Per GCL Lab Reconciliation Re-query: SWAB: COVID diagnostic test swab sample collected on 19Oct2020 is not yet entered in EDC. Please reconcile.' answered with 'data entered' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:25:33
User opened query 'Per GCL Lab Reconciliation Re-query: SWAB: COVID diagnostic test swab sample collected on 19Oct2020 is not yet entered in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:48:00
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19Oct2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:48:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19Oct2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'ILLNESS VISIT ENTERED' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:15:12
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19Oct2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:02:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 15:30:11

US3392112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:30:11

US3392112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:30:11

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'VISIT2'	System	21 Oct 2020 15:30:11



US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '12:54'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '22 Sep 2020 12:54'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '97.6' F	(b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17



US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '81'	(b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'bpm'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '14'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'breaths/min'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '128'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '80'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	21 Oct 2020 15:32:17



US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '14:05'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '22 Sep 2020 14:05'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '98.3' F	(b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17



US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '73'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'bpm'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'breaths/min'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '144'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '84'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:17

US3392112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	21 Oct 2020 15:32:17



US3392112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:46

US3392112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:32:46

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4)	22 Sep 2020 18:37:21
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered empty.	(b) (4)	22 Sep 2020 18:37:21
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

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)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered empty.	(b) (4)	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '22 Sep 2020'	(b) (4)	22 Sep 2020 18:37:21
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '13:29'	(b) (4)	22 Sep 2020 18:37:21



US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '22 Sep 2020 13:29'	System	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brandon Illickal (b) (4)	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'ONCE'	System	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 18:37:21

US3392112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	22 Sep 2020 18:37:41

US3392112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 22SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 22SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:24:55
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 22SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 22SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'UNSCHEDULED SAMPLE COLLECTED ON 22/SEP/2020 IS FOR VISIT 2 DAY 29.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:36:42
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 22SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 22SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:59:58
User entered '22 Sep 2020'	Brandon Illickal (b) (4)	22 Sep 2020 18:37:41

US3392112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '13:05'	(b) (4)	22 Sep 2020 18:37:41

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '22 Sep 2020 13:05'	System	22 Sep 2020 18:37:41



US3392112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:36:12
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Labs drawn for Visit 2 Day 29' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:27:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:00:54
User entered '22 Sep 2020'	Brandon Illickal (b) (4)	22 Sep 2020 18:37:58

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Illickal (b) (4)	22 Sep 2020 18:37:58

US3392112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	22 Sep 2020 18:37:58

US3392112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered '13:00'	(b) (4)	22 Sep 2020 18:37:58

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '22 Sep 2020 13:00'	System	22 Sep 2020 18:37:58

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Illickal (b) (4)	22 Sep 2020 18:37:58

US3392112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'No (N)'	(b) (4)	22 Sep 2020 18:37:58
	Brandon Illickal (b) (4)	

**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:24:17**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered empty.	(b) (4)	22 Sep 2020 18:37:58
	Brandon Illickal (b) (4)	



**US3392112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered empty.	System	22 Sep 2020 18:37:58

US3392112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:14
User entered 'Yes (Y)'	(b) (4)	22 Sep 2020 18:38:02
	Brandon Illickal (b) (4)	

US3392112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '1'	System	22 Sep 2020 18:38:02

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:54:58', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1204072b-e531-446a-a9c8-c91444b0da36' User entered 'Yes (Y)'	System	22 Sep 2020 18:56:15
	System	22 Sep 2020 18:56:15

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:55:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1204072b-e531-446a-a9c8-c91444b0da36' User entered '98.3'	System	22 Sep 2020 18:56:15
	System	22 Sep 2020 18:56:15

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:55:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1204072b-e531-446a-a9c8-c91444b0da36' User entered 'No (N)'	System	22 Sep 2020 18:56:15
	System	22 Sep 2020 18:56:15

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:55:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1204072b-e531-446a-a9c8-c91444b0da36' User entered '22 Sep 2020 13:55'	System	22 Sep 2020 18:56:15
	System	22 Sep 2020 18:56:15



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 13:49'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:15:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024' User entered 'Yes (Y)'	System	23 Sep 2020 02:16:22
	System	23 Sep 2020 02:16:22

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:15:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024' User entered '96.1'	System	23 Sep 2020 02:16:22
	System	23 Sep 2020 02:16:22

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:15:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024'	System	23 Sep 2020 02:16:22
User entered 'Yes (Y)'	System	23 Sep 2020 02:16:22

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:37:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:21:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024'	System	23 Sep 2020 02:16:22
User entered '1'	System	23 Sep 2020 02:16:22

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024' User entered '0'	System	23 Sep 2020 02:16:22
	System	23 Sep 2020 02:16:22



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c6fa79f7-b583-41ed-87fa-041856c46024' User entered '22 Sep 2020 21:16'	System	23 Sep 2020 02:16:22
	System	23 Sep 2020 02:16:22

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 17:14'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 2'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:05:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered 'Yes (Y)'	System	24 Sep 2020 14:06:06
	System	24 Sep 2020 14:06:06

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:05:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered '97.6'	System	24 Sep 2020 14:06:06
	System	24 Sep 2020 14:06:06

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:05:51', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered 'Yes (Y)'	System	24 Sep 2020 14:06:06
	System	24 Sep 2020 14:06:06

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:37:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered '1'	(b) (4), (b) (6)	20 Oct 2020 19:22:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Sep 2020 14:06:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered '1'	System	24 Sep 2020 14:06:06
User entered '1'	System	24 Sep 2020 14:06:06



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered '0'	System	24 Sep 2020 14:06:06
	System	24 Sep 2020 14:06:06

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cf83b560-68c1-4976-af9e-493e12281ac8' User entered '24 Sep 2020 09:06'	System	24 Sep 2020 14:06:06
	System	24 Sep 2020 14:06:06

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 3'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:35:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808' User entered 'Yes (Y)'	System	24 Sep 2020 18:38:27
	System	24 Sep 2020 18:38:27

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:37:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808' User entered '98.3'	System	24 Sep 2020 18:38:27
	System	24 Sep 2020 18:38:27

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:06', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808'	System	24 Sep 2020 18:38:27
User entered 'Yes (Y)'	System	24 Sep 2020 18:38:27



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:40:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:22:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808'	System	24 Sep 2020 18:38:27
User entered '1'	System	24 Sep 2020 18:38:27

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808' User entered '0'	System	24 Sep 2020 18:38:27
	System	24 Sep 2020 18:38:27

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '92739d2c-b80e-4407-bccf-6323f208b808' User entered '24 Sep 2020 13:38'	System	24 Sep 2020 18:38:27
	System	24 Sep 2020 18:38:27

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 4'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered 'Yes (Y)'	System	26 Sep 2020 01:17:12
	System	26 Sep 2020 01:17:12

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered '97.6'	System	26 Sep 2020 01:17:12
	System	26 Sep 2020 01:17:12



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered 'Yes (Y)'	System	26 Sep 2020 01:17:12
	System	26 Sep 2020 01:17:12

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:41:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered '1'	(b) (4), (b) (6)	20 Oct 2020 19:23:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Sep 2020 01:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered '1'	System	26 Sep 2020 01:17:12
User entered '1'	System	26 Sep 2020 01:17:12

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered '0'	System	26 Sep 2020 01:17:12
	System	26 Sep 2020 01:17:12

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'aac1aa12-c77c-4064-99ba-c95b815d75d1' User entered '25 Sep 2020 20:12'	System	26 Sep 2020 01:17:12
	System	26 Sep 2020 01:17:12

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 5'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:51:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '00375fe6-8fe0-49e1-bcfb-961429888759' User entered 'Yes (Y)'	System	27 Sep 2020 01:52:04
	System	27 Sep 2020 01:52:04



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:51:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '00375fe6-8fe0-49e1-bcfb-961429888759' User entered '97.6'	System	27 Sep 2020 01:52:04
	System	27 Sep 2020 01:52:04

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:51:58', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '00375fe6-8fe0-49e1-bcfb-961429888759'	System	27 Sep 2020 01:52:04
User entered 'No (N)'	System	27 Sep 2020 01:52:04

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:01', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '00375fe6-8fe0-49e1-bcfb-961429888759'	System	27 Sep 2020 01:52:04
User entered '26 Sep 2020 20:52'	System	27 Sep 2020 01:52:04

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 6'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:07:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '800d163b-61f6-4dfa-a540-fb1b295917f7' User entered 'Yes (Y)'	System	27 Sep 2020 23:08:08
	System	27 Sep 2020 23:08:08

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:07:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '800d163b-61f6-4dfa-a540-fb1b295917f7' User entered '98.5'	System	27 Sep 2020 23:08:08
	System	27 Sep 2020 23:08:08



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:01', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '800d163b-61f6-4dfa-a540-fb1b295917f7'	System	27 Sep 2020 23:08:08
User entered 'No (N)'	System	27 Sep 2020 23:08:08

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '800d163b-61f6-4dfa-a540-fb1b295917f7' User entered '27 Sep 2020 18:08'	System	27 Sep 2020 23:08:08
	System	27 Sep 2020 23:08:08

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 7'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:28:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d' User entered 'Yes (Y)'	System	28 Sep 2020 22:29:17
	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:28:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d' User entered '98.3'	System	28 Sep 2020 22:29:17
	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d' User entered 'Yes (Y)'	System	28 Sep 2020 22:29:17
	System	28 Sep 2020 22:29:17



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:41:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:23:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d'	System	28 Sep 2020 22:29:17
User entered '1'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d' User entered '0'	System	28 Sep 2020 22:29:17
	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9daaea80-baf8-4169-9838-f2c2a786156d' User entered '28 Sep 2020 17:29'	System	28 Sep 2020 22:29:17
	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Sep 2020 22:29:17
User entered 'Day 8'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:10:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5' User entered 'Yes (Y)'	System	30 Sep 2020 03:11:14
	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:10:53', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5' User entered '98.6'	System	30 Sep 2020 03:11:14
	System	30 Sep 2020 03:11:14



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5'	System	30 Sep 2020 03:11:14
User entered 'Yes (Y)'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:41:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:24:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5'	System	30 Sep 2020 03:11:14
User entered '1'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5' User entered '0'	System	30 Sep 2020 03:11:14
	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ce6bdb7c-ec19-4227-b0bd-395fc39a0cb5' User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:14
	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Sep 2020 22:29:17
User entered 'Day 9'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:05:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered 'Yes (Y)'	System	01 Oct 2020 01:06:26
	System	01 Oct 2020 01:06:26



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered '97.8'	System	01 Oct 2020 01:06:26
	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered 'Yes (Y)'	System	01 Oct 2020 01:06:26
	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 10:41:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered '1'	(b) (4), (b) (6)	20 Oct 2020 19:24:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 01:06:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered '1'	System	01 Oct 2020 01:06:26
User entered '1'	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered '0'	System	01 Oct 2020 01:06:26
	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '5ce4f402-9da5-4778-9a4c-93599870af5d' User entered '30 Sep 2020 20:06'	System	01 Oct 2020 01:06:26
	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	30 Sep 2020 03:11:14
User entered 'Day 10'	System	30 Sep 2020 03:11:14



US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b65bd191-c1dd-4e28-ab4c-89204501fd16' User entered 'Yes (Y)'	System	02 Oct 2020 14:57:33
	System	02 Oct 2020 14:57:33

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:22', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b65bd191-c1dd-4e28-ab4c-89204501fd16' User entered '97.7'	System	02 Oct 2020 14:57:33
	System	02 Oct 2020 14:57:33

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b65bd191-c1dd-4e28-ab4c-89204501fd16'	System	02 Oct 2020 14:57:33
User entered 'No (N)'	System	02 Oct 2020 14:57:33

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b65bd191-c1dd-4e28-ab4c-89204501fd16' User entered '02 Oct 2020 09:57'	System	02 Oct 2020 14:57:33
	System	02 Oct 2020 14:57:33

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '068d4ff1-abb4-460f-a73b-d2dfe3b6e019'	System	22 Sep 2020 18:56:31
User entered 'None (1)'	System	22 Sep 2020 18:56:31



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '068d4ff1-abb4-460f-a73b-d2dfe3b6e019' User entered 'No (N)'	System	22 Sep 2020 18:56:31
	System	22 Sep 2020 18:56:31

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '068d4ff1-abb4-460f-a73b-d2dfe3b6e019' User entered 'No (N)'	System	22 Sep 2020 18:56:31
	System	22 Sep 2020 18:56:31

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '068d4ff1-abb4-460f-a73b-d2dfe3b6e019' User entered 'None (1)'	System	22 Sep 2020 18:56:31
	System	22 Sep 2020 18:56:31

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '068d4ff1-abb4-460f-a73b-d2dfe3b6e019' User entered '22 Sep 2020 13:56'	System	22 Sep 2020 18:56:31
	System	22 Sep 2020 18:56:31

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '22 Sep 2020 13:49'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0'	System	23 Sep 2020 02:17:37
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 02:17:37



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0' User entered 'No (N)'	System	23 Sep 2020 02:17:37
	System	23 Sep 2020 02:17:37

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:16:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0' User entered 'Yes (Y)'	System	23 Sep 2020 02:17:37
	System	23 Sep 2020 02:17:37

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:22', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0' User entered '23'	System	23 Sep 2020 02:17:37
	System	23 Sep 2020 02:17:37

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0' User entered 'None (1)'	System	23 Sep 2020 02:17:37
	System	23 Sep 2020 02:17:37

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '66f41879-5f49-44e4-becd-da0dfd403bb0' User entered '22 Sep 2020 21:17'	System	23 Sep 2020 02:17:37
	System	23 Sep 2020 02:17:37

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '22 Sep 2020 17:14'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 2'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:40:05
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	03 Mar 2021 00:40:37
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:51:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11'	System	24 Sep 2020 14:10:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11' User entered 'No (N)'	System	24 Sep 2020 14:10:53
	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:06:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11' User entered 'Yes (Y)'	System	24 Sep 2020 14:10:53
	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:10:33', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11' User entered '780'	System	24 Sep 2020 14:10:53
	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:10:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11' User entered 'None (1)'	System	24 Sep 2020 14:10:53
	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:10:48', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fe728ea9-3f56-4d96-8739-6139b777ae11' User entered '24 Sep 2020 09:10'	System	24 Sep 2020 14:10:53
	System	24 Sep 2020 14:10:53

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 3'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:40:16
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	Brandon Illickal (b) (4)	03 Mar 2021 00:40:45
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:51:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f56f68f9-63bc-460b-8457-3bc3dc3b15f4'	System	24 Sep 2020 18:39:28
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 18:39:28

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:38:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f56f68f9-63bc-460b-8457-3bc3dc3b15f4'	System	24 Sep 2020 18:39:28
User entered 'No (N)'	System	24 Sep 2020 18:39:28

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:39:16', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f56f68f9-63bc-460b-8457-3bc3dc3b15f4'	System	24 Sep 2020 18:39:28
User entered 'No (N)'	System	24 Sep 2020 18:39:28

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:39:22', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f56f68f9-63bc-460b-8457-3bc3dc3b15f4'	System	24 Sep 2020 18:39:28
User entered 'None (1)'	System	24 Sep 2020 18:39:28

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:39:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f56f68f9-63bc-460b-8457-3bc3dc3b15f4' User entered '24 Sep 2020 13:39'	System	24 Sep 2020 18:39:28
	System	24 Sep 2020 18:39:28

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 4'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:53', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2eea0f6f-b25f-412a-a946-03836a42e020'	System	26 Sep 2020 01:17:24
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 01:17:24

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:12:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2eea0f6f-b25f-412a-a946-03836a42e020'	System	26 Sep 2020 01:17:24
User entered 'No (N)'	System	26 Sep 2020 01:17:24

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2eea0f6f-b25f-412a-a946-03836a42e020' User entered 'No (N)'	System	26 Sep 2020 01:17:24
	System	26 Sep 2020 01:17:24

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:24', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2eea0f6f-b25f-412a-a946-03836a42e020' User entered 'None (1)'	System	26 Sep 2020 01:17:24
	System	26 Sep 2020 01:17:24

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:27', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2eea0f6f-b25f-412a-a946-03836a42e020' User entered '25 Sep 2020 20:13'	System	26 Sep 2020 01:17:24
	System	26 Sep 2020 01:17:24

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 5'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '004e3dc4-351d-468b-9cff-57bab7fef1a7'	System	27 Sep 2020 01:52:42
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 01:52:42

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '004e3dc4-351d-468b-9cff-57bab7fef1a7' User entered 'No (N)'	System	27 Sep 2020 01:52:42
	System	27 Sep 2020 01:52:42

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '004e3dc4-351d-468b-9cff-57bab7fef1a7' User entered 'No (N)'	System	27 Sep 2020 01:52:42
	System	27 Sep 2020 01:52:42

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '004e3dc4-351d-468b-9cff-57bab7fef1a7'	System	27 Sep 2020 01:52:42
User entered 'None (1)'	System	27 Sep 2020 01:52:42

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '004e3dc4-351d-468b-9cff-57bab7fef1a7' User entered '26 Sep 2020 20:52'	System	27 Sep 2020 01:52:42
	System	27 Sep 2020 01:52:42

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 6'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6eb4a4f5-98a1-405a-83d4-71b44765440f' User entered 'None (1)'	System	27 Sep 2020 23:08:38
	System	27 Sep 2020 23:08:38

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:24', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6eb4a4f5-98a1-405a-83d4-71b44765440f' User entered 'No (N)'	System	27 Sep 2020 23:08:38
	System	27 Sep 2020 23:08:38

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6eb4a4f5-98a1-405a-83d4-71b44765440f' User entered 'No (N)'	System	27 Sep 2020 23:08:38
	System	27 Sep 2020 23:08:38

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6eb4a4f5-98a1-405a-83d4-71b44765440f' User entered 'None (1)'	System	27 Sep 2020 23:08:38
	System	27 Sep 2020 23:08:38

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6eb4a4f5-98a1-405a-83d4-71b44765440f' User entered '27 Sep 2020 18:08'	System	27 Sep 2020 23:08:38
	System	27 Sep 2020 23:08:38

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 7'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:24', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '81da8664-4f28-4acc-9f9d-3c70ea5f6c15' User entered 'None (1)'	System	28 Sep 2020 22:29:51
	System	28 Sep 2020 22:29:51

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '81da8664-4f28-4acc-9f9d-3c70ea5f6c15' User entered 'No (N)'	System	28 Sep 2020 22:29:51
	System	28 Sep 2020 22:29:51

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '81da8664-4f28-4acc-9f9d-3c70ea5f6c15' User entered 'No (N)'	System	28 Sep 2020 22:29:51
	System	28 Sep 2020 22:29:51

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '81da8664-4f28-4acc-9f9d-3c70ea5f6c15' User entered 'None (1)'	System	28 Sep 2020 22:29:51
	System	28 Sep 2020 22:29:51

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '81da8664-4f28-4acc-9f9d-3c70ea5f6c15' User entered '28 Sep 2020 17:29'	System	28 Sep 2020 22:29:51
	System	28 Sep 2020 22:29:51

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:24:12
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:40', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:45', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:49', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:56:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:57:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'None (0)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:57:09', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered 'No (N)'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T13:57:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f20405e2-0d44-42bd-b933-6d8761e6356e' User entered '22 Sep 2020 13:57'	System	22 Sep 2020 18:57:14
	System	22 Sep 2020 18:57:14

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 13:49'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 16:19'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:43', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:51', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:55', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:17:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:18:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'None (0)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:19:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered 'No (N)'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-22T21:19:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e31eb32a-1f9e-4cc2-a276-2ed070d00947' User entered '22 Sep 2020 21:19'	System	23 Sep 2020 02:19:41
	System	23 Sep 2020 02:19:41

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '22 Sep 2020 17:14'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 2'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1'	System	24 Sep 2020 14:11:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 14:11:50



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1'	System	24 Sep 2020 14:11:50
User entered 'Some interference with activity (2)'	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:22', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered 'None (0)'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered 'None (0)'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered 'No (N)'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T09:11:45', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'ebb01713-8af3-4818-b1ac-07645678caa1' User entered '24 Sep 2020 09:11'	System	24 Sep 2020 14:11:50
	System	24 Sep 2020 14:11:50

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:37:21



**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 3'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:39:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca' User entered 'No interference with activity (1)'	System	24 Sep 2020 18:40:55
	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:39:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca'	System	24 Sep 2020 18:40:55
User entered 'Some interference with activity (2)'	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca' User entered 'Some interference with activity (2)'	System	24 Sep 2020 18:40:55
	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca' User entered 'No interference with activity (1)'	System	24 Sep 2020 18:40:55
	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca'	System	24 Sep 2020 18:40:55
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:36', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca'	System	24 Sep 2020 18:40:55
User entered 'No interference with activity (1)'	System	24 Sep 2020 18:40:55



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca' User entered 'No (N)'	System	24 Sep 2020 18:40:55
	System	24 Sep 2020 18:40:55

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-24T13:40:53', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '3b4c347e-9603-409b-90c5-4265d493efca' User entered '24 Sep 2020 13:40'	System	24 Sep 2020 18:40:55
	System	24 Sep 2020 18:40:55

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 4'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2' User entered 'None (0)'	System	26 Sep 2020 01:17:38
	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:48', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2'	System	26 Sep 2020 01:17:38
User entered 'Some interference with activity (2)'	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:55', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2'	System	26 Sep 2020 01:17:38
User entered 'No interference with activity (1)'	System	26 Sep 2020 01:17:38



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:13:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2'	System	26 Sep 2020 01:17:38
User entered 'No interference with activity (1)'	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:14:09', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2'	System	26 Sep 2020 01:17:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:14:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2' User entered 'None (0)'	System	26 Sep 2020 01:17:38
	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:14:16', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2' User entered 'No (N)'	System	26 Sep 2020 01:17:38
	System	26 Sep 2020 01:17:38

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-25T20:14:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '2553de20-d429-4810-99a6-7b81e9d16fb2' User entered '25 Sep 2020 20:14'	System	26 Sep 2020 01:17:38
	System	26 Sep 2020 01:17:38

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 5'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:44', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa' User entered 'None (0)'	System	27 Sep 2020 01:53:20
	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa'	System	27 Sep 2020 01:53:20
User entered 'No interference with activity (1)'	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:52:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa'	System	27 Sep 2020 01:53:20
User entered 'No interference with activity (1)'	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:53:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa'	System	27 Sep 2020 01:53:20
User entered 'No interference with activity (1)'	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:53:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa' User entered 'None (0)'	System	27 Sep 2020 01:53:20
	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:53:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa' User entered 'None (0)'	System	27 Sep 2020 01:53:20
	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:53:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa' User entered 'No (N)'	System	27 Sep 2020 01:53:20
	System	27 Sep 2020 01:53:20

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-26T20:53:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a6f8880e-1081-440e-99e0-822172a404aa' User entered '26 Sep 2020 20:53'	System	27 Sep 2020 01:53:20
	System	27 Sep 2020 01:53:20



**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 6'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:45', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:08:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'Some interference with activity (2)'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	27 Sep 2020 23:09:35



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:21', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848'	System	27 Sep 2020 23:09:35
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848' User entered 'No (N)'	System	27 Sep 2020 23:09:35
	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-27T18:09:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8daa58cd-1d3f-47b8-a138-3cf1005bb848' User entered '27 Sep 2020 18:09'	System	27 Sep 2020 23:09:35
	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	22 Sep 2020 18:37:21
User entered 'Day 7'	System	22 Sep 2020 18:37:21

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:29:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c' User entered 'None (0)'	System	28 Sep 2020 22:31:06
	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:15', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c'	System	28 Sep 2020 22:31:06
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:31:06



US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c' User entered 'Some interference with activity (2)'	System	28 Sep 2020 22:31:06
	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:38', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c' User entered 'Some interference with activity (2)'	System	28 Sep 2020 22:31:06
	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c'	System	28 Sep 2020 22:31:06
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:53', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c'	System	28 Sep 2020 22:31:06
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:30:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c' User entered 'No (N)'	System	28 Sep 2020 22:31:06
	System	28 Sep 2020 22:31:06

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-28T17:31:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f716180d-7743-4a5e-80e4-482e8a6b311c' User entered '28 Sep 2020 17:31'	System	28 Sep 2020 22:31:06
	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:37:21

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:37:21



US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cb0200e4-66bb-46d4-bf73-991e4b7112fa' User entered 'No interference with activity (1)'	System	30 Sep 2020 03:11:25
	System	30 Sep 2020 03:11:25

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cb0200e4-66bb-46d4-bf73-991e4b7112fa' User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:25
	System	30 Sep 2020 03:11:25

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Sep 2020 22:31:06
User entered 'Day 9'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:31', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '7a83ca8a-34c9-4054-a0a1-e0ee46d6c5f1'	System	01 Oct 2020 01:06:39
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:06:39

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '7a83ca8a-34c9-4054-a0a1-e0ee46d6c5f1' User entered '30 Sep 2020 20:06'	System	01 Oct 2020 01:06:39
	System	01 Oct 2020 01:06:39



**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	30 Sep 2020 03:11:25
User entered 'Day 10'	System	30 Sep 2020 03:11:25

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6467535e-9c43-4239-a019-5ca1364052df'	System	02 Oct 2020 14:57:45
User entered 'No interference with activity (1)'	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6467535e-9c43-4239-a019-5ca1364052df' User entered '02 Oct 2020 09:57'	System	02 Oct 2020 14:57:45
	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:11:25

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:11:25

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	01 Oct 2020 01:06:39
User entered 'Day 11'	System	01 Oct 2020 01:06:39



US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:10', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '90c80c55-9647-45d9-ac53-ae222ed66bdb' User entered 'No interference with activity (1)'	System	02 Oct 2020 21:04:16
	System	02 Oct 2020 21:04:16

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '90c80c55-9647-45d9-ac53-ae222ed66bdb' User entered '02 Oct 2020 16:04'	System	02 Oct 2020 21:04:16
	System	02 Oct 2020 21:04:16

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:06:39

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:06:39

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 14:57:45
User entered 'Day 12'	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:57:45



**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 21:04:16
User entered 'Day 13'	System	02 Oct 2020 21:04:16

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 21:04:16

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 21:04:16

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '53ba7de6-19ca-4f58-a8f6-6816db40a8dc'	System	30 Sep 2020 03:11:43
User entered 'No interference with activity (1)'	System	30 Sep 2020 03:11:43



US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '53ba7de6-19ca-4f58-a8f6-6816db40a8dc' User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:43
	System	30 Sep 2020 03:11:43

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Sep 2020 22:31:06
User entered 'Day 9'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:41', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f760d01e-ff0c-44ec-a8b4-487f557a9e72'	System	01 Oct 2020 01:06:49
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:06:49

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f760d01e-ff0c-44ec-a8b4-487f557a9e72'	System	01 Oct 2020 01:06:49
User entered '30 Sep 2020 20:06'	System	01 Oct 2020 01:06:49

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 22:31:06

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 22:31:06



US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	30 Sep 2020 03:11:43
User entered 'Day 10'	System	30 Sep 2020 03:11:43

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:51', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8ed2cf37-1599-4ed2-b018-d4952f45ab2e'	System	02 Oct 2020 14:57:59
User entered 'No interference with activity (1)'	System	02 Oct 2020 14:57:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8ed2cf37-1599-4ed2-b018-d4952f45ab2e' User entered '02 Oct 2020 09:57'	System	02 Oct 2020 14:57:59
	System	02 Oct 2020 14:57:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:11:43

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:11:43

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	01 Oct 2020 01:06:49
User entered 'Day 11'	System	01 Oct 2020 01:06:49

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8d6cdfe7-0b63-41f6-9a2e-6cb8eaf5253a' User entered 'Significant; prevents daily activity (3)'	System	02 Oct 2020 21:04:32

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:30', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '8d6cdfe7-0b63-41f6-9a2e-6cb8eaf5253a' User entered '02 Oct 2020 16:04'	System	02 Oct 2020 21:04:32
	System	02 Oct 2020 21:04:32



US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:06:49

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:06:49

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 14:57:59
User entered 'Day 12'	System	02 Oct 2020 14:57:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:57:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:57:59

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 21:04:32
User entered 'Day 13'	System	02 Oct 2020 21:04:32



US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 21:04:32

US3392112

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 21:04:32

US3392112

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '83aa7be7-cb74-4c41-b038-5ed78812bc96' User entered 'None (0)'	System	30 Sep 2020 03:11:52
	System	30 Sep 2020 03:11:52

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:11:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '83aa7be7-cb74-4c41-b038-5ed78812bc96' User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:52
	System	30 Sep 2020 03:11:52

US3392112

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35



**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cbab9529-de6a-4771-80ea-eed45eec41f8' User entered 'None (0)'	System	30 Sep 2020 03:12:14
	System	30 Sep 2020 03:12:14

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'cbab9529-de6a-4771-80ea-eed45eec41f8' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:14
	System	30 Sep 2020 03:12:14

US3392112

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 17:24:17

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '402490ad-b9a7-4334-94d3-3895396c6670' User entered 'None (0)'	System	30 Sep 2020 03:12:22
	System	30 Sep 2020 03:12:22



US3392112

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Chills\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '402490ad-b9a7-4334-94d3-3895396c6670' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:22
	System	30 Sep 2020 03:12:22

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	27 Sep 2020 23:09:35
User entered 'Day 8'	System	27 Sep 2020 23:09:35

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1f6dfb80-47e7-471e-83dc-29fe5e60fb0a' User entered 'No (N)'	System	30 Sep 2020 03:12:34
	System	30 Sep 2020 03:12:34

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-29T22:12:32', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '1f6dfb80-47e7-471e-83dc-29fe5e60fb0a' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:34
	System	30 Sep 2020 03:12:34

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:09:35

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:09:35



US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	28 Sep 2020 22:29:17
User entered 'Day 9'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:52', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '38a59d60-4a1c-46f2-8684-0779929e3a4c' User entered 'No (N)'	System	01 Oct 2020 01:06:57
	System	01 Oct 2020 01:06:57

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-09-30T20:06:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '38a59d60-4a1c-46f2-8684-0779929e3a4c' User entered '30 Sep 2020 20:06'	System	01 Oct 2020 01:06:57
	System	01 Oct 2020 01:06:57

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 22:29:17

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	30 Sep 2020 03:11:14
User entered 'Day 10'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:57:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '87eea238-8515-4eb7-889c-e26391d58466' User entered 'No (N)'	System	02 Oct 2020 14:58:06
	System	02 Oct 2020 14:58:06

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T09:58:03', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '87eea238-8515-4eb7-889c-e26391d58466' User entered '02 Oct 2020 09:58'	System	02 Oct 2020 14:58:06
	System	02 Oct 2020 14:58:06



US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:11:14

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	01 Oct 2020 01:06:26
User entered 'Day 11'	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9c0ad24a-9d5d-4a32-89be-23846f5cb0bf' User entered 'No (N)'	System	02 Oct 2020 21:04:39
	System	02 Oct 2020 21:04:39

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-10-02T16:04:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9c0ad24a-9d5d-4a32-89be-23846f5cb0bf' User entered '02 Oct 2020 16:04'	System	02 Oct 2020 21:04:39
	System	02 Oct 2020 21:04:39

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:06:26

**US3392112**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:24:17**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:06:26

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 14:57:45
User entered 'Day 12'	System	02 Oct 2020 14:57:45



US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:57:45

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
Data entry locked.	System	02 Oct 2020 21:04:16
User entered 'Day 13'	System	02 Oct 2020 21:04:16

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

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 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19

US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 21:04:16



US3392112

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 17:24:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:33:19
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 21:04:16

**US3392112**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:55:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:40:34

US3392112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:55:39
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:40:34

US3392112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:55:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:40:34

US3392112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:55:39
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:40:34

US3392112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:55:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:40:41

US3392112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	29 Sep 2020 15:40:41

US3392112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:33:27



US3392112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:25
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:33:27

US3392112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:33:27

US3392112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:33:27

US3392112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:33:31

**US3392112**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	21 Oct 2020 15:33:31

**US3392112**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 15:34:11

US3392112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:04
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 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)	22 Oct 2020 14:57:40
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'WITH IN WIDOW' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 15:34:37
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Oct 2020 15:34:11
User entered '12 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 15:34:11

US3392112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:34:11



US3392112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:34:11

US3392112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:34:44

**US3392112**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	21 Oct 2020 15:34:44

US3392112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:01:53

US3392112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:01:53

US3392112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:01:53

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'VISIT3'	System	16 Nov 2020 18:01:53

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:03:46



US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:03:46

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '12:37'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '19 Oct 2020 12:37'	System	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '98.7' F	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '86'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'bpm'	System	16 Nov 2020 18:03:46



US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '16'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'breaths/min'	System	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '129'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '80'	(b) (4), (b) (6)	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'mmHg'	System	16 Nov 2020 18:03:46

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43

US3392112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43



US3392112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:03:57

US3392112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:03:57

US3392112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:04:24

US3392112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:04:24

US3392112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
User entered '12:50'	(b) (4), (b) (6)	16 Nov 2020 18:04:24

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered '19 Oct 2020 12:50'	System	16 Nov 2020 18:04:24

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:21:41
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:19:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:19:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:04:30

**US3392112**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	16 Nov 2020 18:04:30



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 64'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you been exposed to someone with 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 21:11:19

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 71'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you been exposed to someone with 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 21:11:19



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered 'Day 78'	System	28 Aug 2020 21:11:19

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you been exposed to someone with 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

US3392112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please 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 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:15:07
Data entry locked.	System	28 Aug 2020 21:11:19
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 21:11:19

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-11-29T11:59:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '792f6ee9-6055-46f8-add3-5d15b6336825' User entered 'No (N)'	System	29 Nov 2020 18:00:03
	System	29 Nov 2020 18:00:03

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-11-29T11:59:47', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '792f6ee9-6055-46f8-add3-5d15b6336825' User entered 'No (N)'	System	29 Nov 2020 18:00:03
	System	29 Nov 2020 18:00:03

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-11-29T11:59:59', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '792f6ee9-6055-46f8-add3-5d15b6336825' User entered '29 Nov 2020 11:59:59'	System	29 Nov 2020 18:00:03
	System	29 Nov 2020 18:00:03

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-10T12:10:57', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6605ae20-320c-40cd-b398-9bb362bed261' User entered 'No (N)'	System	10 Dec 2020 18:11:14
	System	10 Dec 2020 18:11:14

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-10T12:11:08', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6605ae20-320c-40cd-b398-9bb362bed261' User entered 'No (N)'	System	10 Dec 2020 18:11:14
	System	10 Dec 2020 18:11:14



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-10T12:11:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6605ae20-320c-40cd-b398-9bb362bed261' User entered '10 Dec 2020 12:11:12'	System	10 Dec 2020 18:11:14
	System	10 Dec 2020 18:11:14

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-16T18:04:13', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9fda74d8-22ee-484b-b084-715c64ad8bd1' User entered 'No (N)'	System	17 Dec 2020 00:04:42
	System	17 Dec 2020 00:04:42

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-16T18:04:19', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9fda74d8-22ee-484b-b084-715c64ad8bd1' User entered 'No (N)'	System	17 Dec 2020 00:04:42
	System	17 Dec 2020 00:04:42

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-16T18:04:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '9fda74d8-22ee-484b-b084-715c64ad8bd1' User entered '16 Dec 2020 18:04:35'	System	17 Dec 2020 00:04:42
	System	17 Dec 2020 00:04:42

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-20T00:02:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4d5b9c0-6dce-4659-8097-76d031ec7b9c' User entered 'No (N)'	System	20 Dec 2020 06:02:48
	System	20 Dec 2020 06:02:48

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-20T00:02:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4d5b9c0-6dce-4659-8097-76d031ec7b9c' User entered 'No (N)'	System	20 Dec 2020 06:02:48
	System	20 Dec 2020 06:02:48

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-20T00:02:37', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'e4d5b9c0-6dce-4659-8097-76d031ec7b9c' User entered '20 Dec 2020 00:02:37'	System	20 Dec 2020 06:02:48
	System	20 Dec 2020 06:02:48

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:07:28', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d' User entered 'Yes (Y)'	System	29 Dec 2020 18:08:35
	System	29 Dec 2020 18:08:35

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:07:34', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d'	System	29 Dec 2020 18:08:35
User entered 'No (N)'	System	29 Dec 2020 18:08:35

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:07:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d' User entered 'No (N)'	System	29 Dec 2020 18:08:35
	System	29 Dec 2020 18:08:35

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:07:54', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d' User entered 'Yes (Y)'	System	29 Dec 2020 18:08:35
	System	29 Dec 2020 18:08:35

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:08:20', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d'	System	29 Dec 2020 18:08:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 18:08:35

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2020-12-29T12:08:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'fd4312ea-1358-483e-9c3d-dfefb38b632d' User entered '29 Dec 2020 12:08:25'	System	29 Dec 2020 18:08:35
	System	29 Dec 2020 18:08:35

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:07:18', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba' User entered 'Yes (Y)'	System	03 Jan 2021 06:08:43
	System	03 Jan 2021 06:08:43

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:07:26', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba' User entered 'No (N)'	System	03 Jan 2021 06:08:43
	System	03 Jan 2021 06:08:43

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:07:42', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba' User entered 'No (N)'	System	03 Jan 2021 06:08:43
	System	03 Jan 2021 06:08:43

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:07:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba' User entered 'Yes (Y)'	System	03 Jan 2021 06:08:43
	System	03 Jan 2021 06:08:43

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:08:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba'	System	03 Jan 2021 06:08:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 06:08:43

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-03T00:08:23', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '598d95ea-585a-4816-b4bb-632ae53716ba' User entered '03 Jan 2021 00:08:23'	System	03 Jan 2021 06:08:43
	System	03 Jan 2021 06:08:43

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-14T11:49:04', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '985c02cf-29bd-4cfb-b580-7cc459757582'	System	14 Jan 2021 17:49:28
User entered 'No (N)'	System	14 Jan 2021 17:49:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-14T11:49:07', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '985c02cf-29bd-4cfb-b580-7cc459757582'	System	14 Jan 2021 17:49:28
User entered 'No (N)'	System	14 Jan 2021 17:49:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-14T11:49:12', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '985c02cf-29bd-4cfb-b580-7cc459757582' User entered '14 Jan 2021 11:49:12'	System	14 Jan 2021 17:49:28
	System	14 Jan 2021 17:49:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:15:07



US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-19T16:33:25', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '4f5e3034-672e-43f4-822c-e82ac551a39e' User entered 'No (N)'	System	19 Jan 2021 22:33:36

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-19T16:33:29', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '4f5e3034-672e-43f4-822c-e82ac551a39e'	System	19 Jan 2021 22:33:36
User entered 'No (N)'	System	19 Jan 2021 22:33:36

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-19T16:33:33', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '4f5e3034-672e-43f4-822c-e82ac551a39e' User entered '19 Jan 2021 16:33:33'	System	19 Jan 2021 22:33:36
	System	19 Jan 2021 22:33:36

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:15:07

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:10:35', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41' User entered 'Yes (Y)'	System	25 Jan 2021 21:11:28
	System	25 Jan 2021 21:11:28

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:10:39', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41'	System	25 Jan 2021 21:11:28
User entered 'No (N)'	System	25 Jan 2021 21:11:28



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:10:46', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41' User entered 'No (N)'	System	25 Jan 2021 21:11:28
	System	25 Jan 2021 21:11:28

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:10:58', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41' User entered 'Yes (Y)'	System	25 Jan 2021 21:11:28
	System	25 Jan 2021 21:11:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:11:11', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41'	System	25 Jan 2021 21:11:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 21:11:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-01-25T15:11:17', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a86b0cd5-75ba-4364-9938-963636c22f41' User entered '25 Jan 2021 15:11:17'	System	25 Jan 2021 21:11:28
	System	25 Jan 2021 21:11:28

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-02-18T11:59:50', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b27a7f12-4feb-4aef-9bb5-cae2b2d2aff4' User entered 'No (N)'	System	18 Feb 2021 18:00:11
	System	18 Feb 2021 18:00:11

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-02-18T11:59:56', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b27a7f12-4feb-4aef-9bb5-cae2b2d2aff4' User entered 'No (N)'	System	18 Feb 2021 18:00:11
	System	18 Feb 2021 18:00:11

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-02-18T12:00:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'b27a7f12-4feb-4aef-9bb5-cae2b2d2aff4'	System	18 Feb 2021 18:00:11
User entered '18 Feb 2021 12:00:00'	System	18 Feb 2021 18:00:11



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-18T12:22:05-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '07212089-18fb-4f60-b20e-8fa9de30afe9'	System	18 Mar 2021 17:22:20
User entered 'No (N)'	System	18 Mar 2021 17:22:20

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-18T12:22:08-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '07212089-18fb-4f60-b20e-8fa9de30afe9'	System	18 Mar 2021 17:22:20
User entered 'No (N)'	System	18 Mar 2021 17:22:20

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-18T12:22:17-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '07212089-18fb-4f60-b20e-8fa9de30afe9' User entered '18 Mar 2021 12:22:17'	System	18 Mar 2021 17:22:20
	System	18 Mar 2021 17:22:20

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-28T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f9f8520e-fea6-4c11-8d27-37d6f4acf9c7'	System	28 Mar 2021 05:02:58
User entered 'No (N)'	System	28 Mar 2021 05:02:58

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-28T00:02:50-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f9f8520e-fea6-4c11-8d27-37d6f4acf9c7'	System	28 Mar 2021 05:02:58
User entered 'No (N)'	System	28 Mar 2021 05:02:58

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-28T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'f9f8520e-fea6-4c11-8d27-37d6f4acf9c7'	System	28 Mar 2021 05:02:58
User entered '28 Mar 2021 00:02:55'	System	28 Mar 2021 05:02:58



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:15:07

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:05:17-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered 'Yes (Y)'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:05:21-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered 'No (N)'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:05:41-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered 'Yes (Y)'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '0'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered '1'	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:29-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '0'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:06:54-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5'	System	04 Apr 2021 06:07:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Apr 2021 06:07:25



US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:07:09-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered 'No (N)'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-04T01:07:16-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '59c01d33-40e7-4c89-accb-693fcd13a0c5' User entered '04 Apr 2021 01:07:16'	System	04 Apr 2021 06:07:25
	System	04 Apr 2021 06:07:25

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-20T12:14:52-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c063322b-322d-443b-aecc-883b4faf0215'	System	20 Apr 2021 17:15:07
User entered 'No (N)'	System	20 Apr 2021 17:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-20T12:14:58-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c063322b-322d-443b-aecc-883b4faf0215'	System	20 Apr 2021 17:15:07
User entered 'No (N)'	System	20 Apr 2021 17:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-20T12:15:02-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'c063322b-322d-443b-aecc-883b4faf0215'	System	20 Apr 2021 17:15:07
User entered '20 Apr 2021 12:15:02'	System	20 Apr 2021 17:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-25T00:04:04-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6d7d339e-160d-41f3-b95e-06c30afd7193'	System	25 Apr 2021 05:05:52
User entered 'No (N)'	System	25 Apr 2021 05:05:52

US3392112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:17

Have you been exposed to someone with 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 (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-25T00:04:09-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6d7d339e-160d-41f3-b95e-06c30afd7193'	System	25 Apr 2021 05:05:52
User entered 'No (N)'	System	25 Apr 2021 05:05:52



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-04-25T00:04:12-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: '6d7d339e-160d-41f3-b95e-06c30afd7193'	System	25 Apr 2021 05:05:52
User entered '25 Apr 2021 00:04:12'	System	25 Apr 2021 05:05:52

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:15:07



**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:15:07

**US3392112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:24:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:15:07
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:15:07



US3392112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-18T12:22:43-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a924eb3a-9070-43aa-927a-6bf00d1efbdc'	System	18 Mar 2021 17:23:09
User entered 'No (N)'	System	18 Mar 2021 17:23:09

**US3392112**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:06:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (08EE4629-0C69-467B-880D-2645D44E8CF3)', Time: '2021-03-18T12:22:48-05:00', User OID: 'PatientReportedOutcome (US3392112)', ODM File OID: 'a924eb3a-9070-43aa-927a-6bf00d1efbdc' User entered '18 Mar 2021 12:22:48'	System	18 Mar 2021 17:23:09
	System	18 Mar 2021 17:23:09

**US3392112**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:55:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 19:41:44

US3392112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:55:34
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:41:44

US3392112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:55:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:41:44

US3392112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:55:34
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 19:41:44

US3392112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:55:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:41:50

**US3392112**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:43
User entered 'I'	System	08 Dec 2020 19:41:50



US3392112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:04:01

US3392112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered '7 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 18:04:01

US3392112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Dec 2020 18:04:01

US3392112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:04:01

US3392112

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:04:11

**US3392112**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:12
User entered 'I'	System	10 Dec 2020 18:04:11

**US3392112**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	18 Feb 2021 21:45:56
	(b) (4)	

**US3392112**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered '18 Jan 2021'	Heather Salisbury (b) (4)	18 Feb 2021 21:45:56
	(b) (4)	



**US3392112**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	18 Feb 2021 21:45:56
	(b) (4)	

US3392112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	18 Feb 2021 21:45:56
	(b) (4)	

US3392112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
	(b) (4)	
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	18 Feb 2021 21:46:00
	(b) (4)	

**US3392112**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:23
User entered 'I'	System	18 Feb 2021 21:46:00

**US3392112**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:24:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	18 Feb 2021 21:46:11

US3392112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered '18 Feb 2021'	Heather Salisbury (b) (4)	18 Feb 2021 21:46:11

US3392112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	18 Feb 2021 21:46:11

US3392112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	Heather Salisbury (b) (4)	18 Feb 2021 21:46:11



US3392112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	18 Feb 2021 21:46:51

**US3392112**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:35
User entered 'I'	System	18 Feb 2021 21:46:51

US3392112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:47:50

US3392112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:47:50

US3392112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:47:50

**US3392112**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered 'VISIT4'	System	08 Mar 2021 21:47:50

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'No (N)'	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19



US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered empty.	System	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

**US3392112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered empty.	System	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19



US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered empty.	System	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered empty.	System	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4)	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered empty.	System	01 Apr 2021 16:10:19

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16

US3392112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16

US3392112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:47:56



US3392112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:47:56

US3392112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:48:16

US3392112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:48:16

**US3392112**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered '14:05'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:48:16

**US3392112**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered '8 Mar 2021 14:05'	System	08 Mar 2021 21:48:16

US3392112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:48:20

**US3392112**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:16
User entered 'I'	System	08 Mar 2021 21:48:20

**US3392112**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:57:32
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:57:53



US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:17

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:57:32
User entered '14:32'	(b) (4), (b) (6)	19 Nov 2020 20:57:53

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:17

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '18 Nov 2020 14:32'	System	19 Nov 2020 20:57:53

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:17

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:57:32
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	19 Nov 2020 20:57:53

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:17

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:57:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:59:03
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:57:53

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:18:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:18:10
User entered 'No (N)' reason for change: New Information	Brandon Illickal (b) (4)	20 Nov 2020 19:18:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:59:48
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:59:48



US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:28
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:59:48

US3392112

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '0'	System	20 Nov 2020 19:18:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:42
User entered '19 Oct 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:01:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:01:50
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 19:55:04



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:46
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:01:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:48
User entered '19 Oct 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:01:59
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:35:52
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:34:47
Query 'Data is required. Please complete.' answered with 'Data deleted per query because of duplication' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:02:08
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:54:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:54:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:37
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 19:55:04

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '0'	System	19 Nov 2020 19:55:04



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '17 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:04:18

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '18 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 20:05:31



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 20:05:31

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:08:29



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '98.7' F reason for change: Data Entry Error	Brandon Illickal (b) (4)	24 Nov 2020 20:35:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:08:29

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '20 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:12:26



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:12:26



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '21 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:14:07

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '22 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:15:14



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:16:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:16:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:16:20
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 21:15:14

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '23 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:19:10



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:42:47
User closed query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done".' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:05:27
Query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done".' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	25 Feb 2021 21:54:12
DataPoint Un-verified.	Brandon Illickal (b) (4)	25 Feb 2021 21:54:03
User entered 'None (None)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	25 Feb 2021 21:54:03
User opened query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done".' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:19:10

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '24 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:20:28



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:20:28



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '25 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:21:46

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '26 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:23:47



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:23:47

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '27 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:25:38



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:25:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '28 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:27:41



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:27:41



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '29 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:29:38

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:32:32
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '30 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:30:50



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:50

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '31 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:32:32



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:32:32

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '01 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '1 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:33:56



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:33:56



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '02 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '2 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '95' reason for change: Data Entry Error	Brandon Illickal (b) (4)	24 Nov 2020 20:37:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:35:48

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '03 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '3 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:36:59



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:36:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '04 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '4 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:38:16



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:38:16

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '05 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '5 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:40:34



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:40:34



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '06 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:40:38
User entered '6 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:24:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:38:39
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:42:05

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:32
User closed query 'The Date of Visit is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Apr 2021 22:37:45
User entered '09 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:45
User opened query 'The Date of Visit is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Apr 2021 22:37:38
User entered '09 Nov 2019' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:43:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered '09 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:41:10
User entered '9 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:44:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:24:27



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:43:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 09:17:15
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE ENTERED' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 20:48:44
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	19 Nov 2020 20:24:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:38
User entered '09 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:39:02
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'This visit was a saliva sample. per protocol a diagnosis of covid-19 is determine by nasopharyngeal swab.' (Site from DM).	Brandon Illickal (b) (4)	06 Apr 2021 21:43:22
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:30:14
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Date of Test](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Nov 2020 22:41:10
User entered '9 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:55
User closed query 'Per GCL Lab Recon: Saliva: RQ: Response noted, however since this Illness DAY 28 Saliva sample dated 09 NOV 2020 is already updated in the corresponding Saliva collection log form for Illness visit dated 19 OCT 2020.Please kindly delete this folder and form as it is creating duplication of data.Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:17:04
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Per GCL Lab Recon: Saliva: RQ: Response noted, however since this Illness DAY 28 Saliva sample dated 09 NOV 2020 is already updated in the corresponding Saliva collection log form for Illness visit dated 19 OCT 2020.Please kindly delete this folder and form as it is creating duplication of data.Thank you.' answered with 'per sponsor request data has been removed' (Site from DM).	Brandon Illickal (b) (4)	19 Apr 2021 20:45:17
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:45:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User opened query 'Per GCL Lab Recon: Saliva: RQ: Response noted, however since this Illness DAY 28 Saliva sample dated 09 NOV 2020 is already updated in the corresponding Saliva collection log form for Illness visit dated 19 OCT 2020.Please kindly delete this folder and form as it is creating duplication of data.Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:50:59

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

Type of Test Performed

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Per EDC, 09NOV2020 is updated under covid 19 Assessment and the same is updated under Illness visit please verify and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:44:19
Query 'Per GCL Lab Reconciliation: Per EDC, 09NOV2020 is updated under covid 19 Assessment and the same is updated under Illness visit please verify and update accordingly.Thanks' answered with 'The saliva sample is from the convalescent period with Illness D1 date of 19OCT2020' (Site from DM).	Brandon Illickal (b) (4)	06 Apr 2021 21:45:33
User opened query 'Per GCL Lab Reconciliation: Per EDC, 09NOV2020 is updated under covid 19 Assessment and the same is updated under Illness visit please verify and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:26:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered 'Saliva Test (Saliva Test)'	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:59:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 14:36:58
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	19 Apr 2021 22:37:38
Query 'Data is required. Please complete.' answered with 'per sponsor request data has been removed' (Site from System).	Brandon Illickal (b) (4)	19 Apr 2021 20:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 15:47:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:47:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:24:27



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:36
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:17

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered 'I'	System	19 Nov 2020 20:24:27

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43



US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

US3392112

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:24:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:56:46
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:26:43

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '21 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04



US3392112

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '22 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '25 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

US3392112

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04



**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '27 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '01 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:54:58
User entered '1 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered '09 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:54:58
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04



US3392112

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:54:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:24:04

**US3392112**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:22:57
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:24:04

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 3 (Day 3)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

**US3392112**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 5 (Day 5)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13



US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 7 (Day 7)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 9 (Day 9)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

**US3392112**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 14 (Day 14)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13



US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 21 (Day 21)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:17

[Visit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User accepted default value 'Day 28 (Day 28)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:46:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	24 Nov 2020 21:36:52
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:16:13

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:06:48
User closed query 'Please reconcile and add all required COVID assessment pages (contact, symptom log, diagnostic page and severity page as D21 saliva was positive. You must add a second COVID assessment folder (diagnostic page) to record the D1 swab that was negative' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:28:57
User closed query 'Please reconcile and enter COVID 19 AE as D21 saliva sample was positive' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:27:29
Query 'Please reconcile and enter COVID 19 AE as D21 saliva sample was positive' answered with 'COVID AE ADDED' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:32:53
Query 'Please reconcile and add all required COVID assessment pages (contact, symptom log, diagnostic page and severity page as D21 saliva was positive. You must add a second COVID assessment folder (diagnostic page) to record the D1 swab that was negative' answered with 'PAGES WERE ADDED AND ADDITIONAL COVID ASSESSMENT FOLDER ADDED TO INDICATE NEGATIVE DAY 1 NP SWAB AND POSITIVE DAY 21 SALIVA TEST. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:32:38
User opened query 'Please reconcile and enter COVID 19 AE as D21 saliva sample was positive' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:30:43
User opened query 'Please reconcile and add all required COVID assessment pages (contact, symptom log, diagnostic page and severity page as D21 saliva was positive. You must add a second COVID assessment folder (diagnostic page) to record the D1 swab that was negative' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:30:18
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Nov 2020 17:49:16



US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:06:48
User entered '19 Oct 2020'	Brandon Illickal (b) (4)  	12 Nov 2020 17:49:16

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:06:48
User entered 'Clinic (Clinic)'	Brandon Illickal (b) (4)  	12 Nov 2020 17:49:16

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Nov 2020 17:49:16

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per CDM: This appears to be a duplicate of Vital signs collected for Visit 3 Day 57 on 19OCT2020, please review and clarify or update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:54:56
Query 'Per CDM: This appears to be a duplicate of Vital signs collected for Visit 3 Day 57 on 19OCT2020, please review and clarify or update accordingly. ' answered with 'Illness visit occurred on the same day as Visit 3. Please advise if one set of vitals should be deleted. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 19:44:26
User opened query 'Per CDM: This appears to be a duplicate of Vital signs collected for Visit 3 Day 57 on 19OCT2020, please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:22:31
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '19 Oct 2020'	Brandon Illickal (b) (4)  	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '12:37'	Brandon Illickal (b) (4)  	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:37'	System	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
	(b) (4)	
DataPoint set to visible.	System	01 Apr 2021 19:07:15
DataPoint set to invisible.	System	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '58.0' in	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09
DataPoint set to visible.	System	12 Nov 2020 17:49:16



US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
	(b) (4)	
DataPoint set to visible.	System	01 Apr 2021 19:07:15
DataPoint set to invisible.	System	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '169.0' lb	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09
DataPoint set to visible.	System	12 Nov 2020 17:49:16

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '98.7' F	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered 'Oral (Oral)'	Brandon Illickal (b) (4)  	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered empty.	Brandon Illickal (b) (4)  	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '86'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '16'	Brandon Illickal (b) (4)  	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Nov 2020 17:51:09



US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '129'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:36
User entered '80'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:09

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 17:51:09

US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:31:36
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 21:30:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 21:30:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	24 Nov 2020 21:30:30
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:35:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:35:07
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:19

US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:31:36
User entered '19 Oct 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	24 Nov 2020 21:30:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 20:35:07
User entered '19 Oct 2020'	Brandon Illickal (b) (4)	12 Nov 2020 17:51:19

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:55:12
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:52:25
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Nov 2020 17:52:04

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:08:57
User entered '19 Oct 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:55:21
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	12 Nov 2020 17:52:25
User entered '19 Oct 2020'	Brandon Illickal (b) (4)	12 Nov 2020 17:52:04



US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:43:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 13:29:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:57:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:52:44
Query 'Data is required. Please complete.' answered with 'data removed and entered on convalescence visit day 28 form' (Site from System).	Brandon Illickal (b) (4)	17 Mar 2021 19:42:23
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:41:47
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:23:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:43:48
User entered '18 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:57:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:52:44
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:23:32
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:43:48
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:57:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:52:44
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:23:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:57:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:52:44
User entered empty.	System	17 Mar 2021 19:41:47
User entered 'SICKD1'	System	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 13:31:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
Query 'Data is required. Please complete.' answered with 'data removed and entered on convalescence visit day 28 form' (Site from System).	Brandon Illickal (b) (4)	17 Mar 2021 19:43:10
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:43:02
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '18 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '14:40' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '14:40'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 14:40'	System	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
User entered empty.	System	17 Mar 2021 19:43:02
User entered '18 Nov 2020 14:40'	System	19 Nov 2020 20:52:15



US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
DataPoint Un-verified.	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint set to visible.	System	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint set to invisible.	System	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:40:23
Query 'Data is required. Please provide.' answered with 'NOT DONE AS NOT REQUIRED' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 20:52:59
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 20:52:15
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:15
DataPoint set to visible.	System	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
DataPoint Un-verified.	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint set to visible.	System	01 Apr 2021 19:07:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint set to invisible.	System	17 Mar 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:40:27
Query 'Data is required. Please provide.' answered with 'NOT DONE AS NOT REQUIRED' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 20:53:03
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 20:52:15
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:15
DataPoint set to visible.	System	19 Nov 2020 20:51:01

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '98.9' F reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '98.9' F	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '84' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '84'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
User entered empty.	System	17 Mar 2021 19:43:02
User entered 'bpm'	System	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '16' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '16'	(b) (4), (b) (6)	19 Nov 2020 20:52:15



US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
User entered empty.	System	17 Mar 2021 19:43:02
User entered 'breaths/min'	System	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '141' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '141'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
User entered empty.	System	17 Mar 2021 19:43:02
User entered 'mmHg'	System	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:28
User entered '82' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:17
User entered '82'	(b) (4), (b) (6)	19 Nov 2020 20:52:15

US3392112

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 19:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00
User entered empty.	System	17 Mar 2021 19:43:02
User entered 'mmHg'	System	19 Nov 2020 20:52:15

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Height \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00

**US3392112**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:00

US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 13:31:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:14
Query 'Data is required. Please complete.' answered with 'data removed and entered on convalescence visit day 28 form' (Site from System).	Brandon Illickal (b) (4)	17 Mar 2021 19:43:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:43:22
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:22
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:53:29



US3392112

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:47
User entered '18 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:09:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:14
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:22
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:32:53
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:53:29

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:44:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 13:31:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:10:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:23
Query 'Data is required. Please complete.' answered with 'data removed and entered on convalescence visit day 28 form' (Site from System).	Brandon Illickal (b) (4)	17 Mar 2021 19:43:39
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:43:35
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:35
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:53:49

US3392112

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:44:58
User entered '18 Nov 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Apr 2021 19:10:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Apr 2021 18:58:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Mar 2021 19:53:23
DataPoint Un-verified.	Brandon Illickal (b) (4)	17 Mar 2021 19:43:35
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 19:43:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:27
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:53:49

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:38
User entered 'No (N)'	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:03

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:38
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:03

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:38
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:03

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	20 Nov 2020 19:17:03

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14



US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:14

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:14

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:17:14



US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:14

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:50
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:14

**US3392112**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:24:17**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:17:14

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:36:00
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Nov 2020 19:17:21

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:36:00
User entered empty.	Brandon Illickal (b) (4)	20 Nov 2020 19:17:21



US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:36:26
User entered 'NA (COVID-19 Negative) (NA)'	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:35

US3392112

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:36:26
User entered empty.	Brandon Illickal (b) (4)  	20 Nov 2020 19:17:35

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:00:47

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:40
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:00:47

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Jan 2021 21:00:47

**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:24:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:00:47

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:04:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:24:30



US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:12:06
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:04:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 20:04:35
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:27:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:24:30

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:40:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:40:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:24:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:46:46
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 21:02:44

**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:24:17**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User entered empty.	System	14 Jan 2021 21:02:44



**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:24:17**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User entered empty.	System	14 Jan 2021 21:02:44

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:03:56

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:01
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:03:56

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:01
User entered '12:18'	(b) (4), (b) (6)	14 Jan 2021 21:03:56

**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:24:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User entered '14 Jan 2021 12:18'	System	14 Jan 2021 21:03:56

**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:24:17**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:04:09

US3392112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:12
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:04:09

**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:24:17**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:12
User entered '12:12'	(b) (4), (b) (6)	14 Jan 2021 21:04:09



**US3392112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:24:17**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:38
User entered '14 Jan 2021 12:12'	System	14 Jan 2021 21:04:09

US3392112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:29
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE (start date: Day 1; end date: Day 11) and Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 11) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:29:51
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 2 - 23SEP2020; end date: Day 11 - 02OCT2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	21 Apr 2021 13:29:49
' (Site from DM).		
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 152, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.	(b) (4), (b) (6)	21 Apr 2021 13:29:47
' (Site from DM).		

US3392112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 152, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'subject had acute kidney injury' (Site from DM).	Brandon Illickal (b) (4)	20 Apr 2021 21:04:08
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE (start date: Day 1; end date: Day 11) and Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 11) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'AE form updated' (Site from DM).	Brandon Illickal (b) (4)	20 Apr 2021 21:03:38
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 2 - 23SEP2020; end date: Day 11 - 02OCT2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'AE form updated' (Site from DM).	Brandon Illickal (b) (4)	20 Apr 2021 21:03:36
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE (start date: Day 1; end date: Day 11) and Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 11) persist beyond Day 7. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:23:29

US3392112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA persist beyond Day 7 (start date: Day 2 - 23SEP2020; end date: Day 11 - 02OCT2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:04:29
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 152, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:40:30

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:52
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:39:55
User entered	System	30 Dec 2020 15:38:45
'USA-US119-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	30 Dec 2020 15:38:45

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'PV Query: Please provide underlying etiology of the small bowel obstruction, if known. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:13:26
Query 'PV Query: Please provide underlying etiology of the small bowel obstruction, if known. If unknown, please state so.' answered with 'ETIOLOGY UNKNOWN' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:47:38
User opened query 'PV Query: Please provide underlying etiology of the small bowel obstruction, if known. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:25:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 21:56:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	29 Dec 2020 21:56:23
Data point term sent to Coder	System	29 Dec 2020 21:55:08
User entered 'small bowel obstruction'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Yes (Y)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'No (N)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27



US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'No (N)'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '27 Dec 2020'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Jan 2021 20:51:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:51:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Jan 2021 20:50:15
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Jan 2021 20:50:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Jan 2021 20:50:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Jan 2021 20:50:15
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:50:15
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:13:35
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'THE ADVERSE EVENT IS STILL ONGOING TO SITE'S KNOWLEDGE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 20:02:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:24:32
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 21:54:27



US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	29 Dec 2020 22:31:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Yes (Y)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 06:05:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject is still admitted' (Site from System).	Brandon Illickal (b) (4)	29 Dec 2020 21:55:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Dec 2020 21:54:40
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	29 Dec 2020 21:54:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Dec 2020 21:54:40
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	29 Dec 2020 21:54:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	29 Dec 2020 21:54:27
User entered '0'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '27 Dec 2020'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:29:39
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'DATA BECAME AVAILAVBLE TO SITE VIA PHONE CALL PATIENT INTERVIEW.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:51:49
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:49:28
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:03:14
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'No (N)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27



US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'I'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered 'Not Applicable (NOT APPLICABLE)'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27



US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'con meds updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:29:22
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	Brandon Illickal (b) (4)	09 Mar 2021 23:52:02
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 07:48:12
	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered '0'	Brandon Illickal (b) (4)  	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:14:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:50:44
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'WILL UPDATED AE WHEN APPLICABLE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:48:39
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:24:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User entered empty.	Brandon Illickal (b) (4)	29 Dec 2020 21:54:27

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:52
User closed query 'PV Query: Please provide signs and symptoms, and when they started.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:35:24
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)	10 Mar 2021 15:35:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:35:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:34:49
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:34:46
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL WITH SMALL BOWEL OBSTRUCTION. describes the pain is a crampy sensation in her left lower quadrant region.' reason for change: Data Entry Error	Brandon Illickal (b) (4)	10 Mar 2021 00:11:16
Query 'PV Query: Please provide signs and symptoms, and when they started.' answered with 'narrative updated' (Site from Safety).	Brandon Illickal (b) (4)	10 Mar 2021 00:10:18

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records have been sent to Safety_Moderna@iqvia.com' (Site from Safety).	Brandon Illickal (b) (4)	10 Mar 2021 00:10:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Brandon Illickal (b) (4)	09 Mar 2021 23:52:53
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records sent' (Site from Safety).	Brandon Illickal (b) (4)	09 Mar 2021 23:52:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'medical records sent.' (Site from Safety).	Brandon Illickal (b) (4)	09 Mar 2021 23:52:35
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL WITH SMALL BOWEL OBSTRUCTION. WILL UPDATE FURTHER WHEN HOSPITAL RECORDS ARE RECEIVED. SUBJECT CONTACTED ON 06/JAN/2002 AND REPORTED DISCHARGE FROM HOSPITAL ON 30/DEC/2020.' reason for change: Data Entry Error	Brandon Illickal (b) (4)	09 Mar 2021 23:48:49
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:24:59
User opened query 'PV Query: Please provide signs and symptoms, and when they started.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:24:46

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:24:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:24:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:24:11
User closed query 'PV Query: Please provide signs and symptoms, and when they started.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:14:37
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:14:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:14:29
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)	07 Jan 2021 15:14:24

US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:14:19
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL WITH SMALL BOWEL OBSTRUCTION. WILL UPDATE FURTHER WHEN HOSPITAL RECORDS ARE RECEIVED. SUBJECT CONTACTED ON 06/JAN/2002 AND REPORTED DISCHARGE FROM HOSPITAL ON 30/DEC/2020. MEDICAL RECORDS HAVE NOT YET BECOME AVAILABLE TO SITE.' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 20:54:01
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'MEDICAL RECORDS RELATED TO EVENT NOT AVAILABLE TO SITE AT THIS GIVEN POINT IN TIME.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:50:04
Query 'PV Query: Please provide signs and symptoms, and when they started.' answered with 'MEDICAL RECORDS RELATED TO EVENT NOT AVAILABLE TO SITE AT THIS GIVEN POINT IN TIME.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:49:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'MEDICAL RECORDS RELATED TO EVENT NOT AVAILABLE TO SITE AT THIS GIVEN POINT IN TIME.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:49:49



US3392112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'HOSPITAL RECORDS NOT AVAILABLE TO SITE AT THIS GIVEN POINT IN TIME.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:49:30
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'HOSPITAL RECORDS NOT AVAILABLE TO SITE AT THIS GIVEN POINT IN TIME.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 19:49:27
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:46:42
User opened query 'PV Query: Please provide signs and symptoms, and when they started.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:25:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:25:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:24:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 20:23:59

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject was admitted to hospital with small bowel obstruction. will update further when hospital records are received.'	Brandon Illickal (b) (4) [REDACTED] [REDACTED]	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Dec 2020 21:54:27

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:03:47
Data point term sent to Coder	System	20 Apr 2021 21:02:39
User entered 'muscle aches'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11



US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '24 Sep 2020'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User entered empty.	System	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '02 Oct 2020'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11



US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User entered empty.	System	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11



US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Related (RELATED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'None (NONE)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11



US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'l'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User entered '0'	System	20 Apr 2021 21:02:11

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14
User entered '0'	System	20 Apr 2021 21:02:11



US3392112

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:14

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:24:17**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:04:39
Data point term sent to Coder	System	20 Apr 2021 21:03:42
User entered 'fatigue'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '24 Sep 2020'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58



US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User entered empty.	System	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '02 Oct 2020'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User entered empty.	System	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58



US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58



US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Related (RELATED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'None (NONE)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'l'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58



US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User entered '0'	System	20 Apr 2021 21:02:58

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20
User entered '0'	System	20 Apr 2021 21:02:58

US3392112

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:05:20

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:08:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:30
User entered		
'USA-US119-2021-mRNA-1273-P301000010'	System	21 Apr 2021 15:35:24
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 15:35:24

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:06:37
Data point term sent to Coder	System	20 Apr 2021 21:05:45
User entered 'acute kidney injury'	Brandon Illickal (b) (4)   	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33



US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '26 Feb 2021'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '01 Mar 2021'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33



**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
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	20 Apr 2021 21:06:21
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	20 Apr 2021 21:05:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Apr 2021 21:05:44
User entered 'No (N)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		20 Apr 2021 21:06:40
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		20 Apr 2021 21:06:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Apr 2021 21:06:21
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Apr 2021 21:06:21
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '26 Feb 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Apr 2021 21:06:21
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '01 Mar 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Apr 2021 21:06:21
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33



US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Apr 2021 21:06:40
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Not Applicable (NOT APPLICABLE)'	Brandon Illickal (b) (4)  	20 Apr 2021 21:05:33



US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'I'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered '0'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:57:41
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:47:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:47:28
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), (b) (6)	29 Apr 2021 20:47:27
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:47:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:47:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:20:30
User entered 'Subject was admitted to ED and received IV fluids for acute kidney injury. Medical records were sent to sponsor on 09MAR2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 18:20:30

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'records sent to sponsor on 09Mar2021' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:03:30
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'records sent to sponsor on 09Mar2021' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:03:11
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 'records sent to sponsor on 09Mar2021' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:02:01
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'records sent to sponsor on 09Mar2021' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:01:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'no record of covid test performed in medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:01:07
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:53:21

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2894 of 3359

US3392112

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:17

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:52:37
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).	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:52:20
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:52:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:08:30
User entered empty.	Brandon Illickal (b) (4)	20 Apr 2021 21:05:33



**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 21:05:44
User entered '0'	System	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:05:33

**US3392112**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 21:06:40

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:17

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:29
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per ETRTR: According to SAE ACUTE KIDNEY INJURY page, subject was given Conmeds. Kindly record all relevant conmeds in Conmed log page.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:34:08
Query 'Per ETRTR: According to SAE ACUTE KIDNEY INJURY page, subject was given Conmeds. Kindly record all relevant conmeds in Conmed log page.' answered with 'con meds updated' (Site from CRA).	Brandon Illickal (b) (4)	22 Apr 2021 16:38:19
User opened query 'Per ETRTR: According to SAE ACUTE KIDNEY INJURY page, subject was given Conmeds. Kindly record all relevant conmeds in Conmed log page.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 09:53:14
User closed query 'Per ETRTR: According to SAE "Small Bowel Obstruction" page, Medication was provided for SAE. Please complete data entry for medication(s) dosed for "Small Bowel Obstruction SAE or reconcile data, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 14:42:10
Query 'Per ETRTR: According to SAE "Small Bowel Obstruction" page, Medication was provided for SAE. Please complete data entry for medication(s) dosed for "Small Bowel Obstruction SAE or reconcile data, thanks.' answered with 'updated' (Site from CRA).	Brandon Illickal (b) (4)	09 Mar 2021 23:54:06
User opened query 'Per ETRTR: According to SAE "Small Bowel Obstruction" page, Medication was provided for SAE. Please complete data entry for medication(s) dosed for "Small Bowel Obstruction SAE or reconcile data, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 14:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:44:38
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:30:46

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:17

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'DATA WAS ENTERED' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:58:02
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:59:08
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:59:08
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'DATA ENTERED' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:39:51
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:42:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	30 Sep 2020 18:33:38
User entered 'No (N)'	Brandon Illickal (b) (4)	31 Aug 2020 23:05:14

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:34:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:34:55
Data point term sent to Coder	System	30 Sep 2020 18:34:27
User entered 'ibuprofen'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:58:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'DID NOT MEET THE AE CRITERIA' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:38:54



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM). User entered 'injection site pain'	(b) (4), (b) (6) [REDACTED]  Brandon Illickal (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 08:57:07           30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '800'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	30 Sep 2020 18:34:26
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	30 Sep 2020 18:34:26
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	30 Sep 2020 18:34:15
User entered 'once (ONCE)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '29 Aug 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '29 Aug 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	30 Sep 2020 18:34:26
User entered '29 Sep 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	30 Sep 2020 18:34:15

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User entered empty.	System	30 Sep 2020 18:34:15

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User entered empty.	System	30 Sep 2020 18:34:15

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:05
User entered empty.	System	30 Sep 2020 18:34:15



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 00:31:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	03 Mar 2021 00:31:48
Data point term sent to Coder Coding entries removed.	System Brandon Illickal (b) (4)	03 Mar 2021 00:31:15 03 Mar 2021 00:31:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:35:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Sep 2020 18:35:51
Data point term sent to Coder User entered 'ibuprofen'	System Brandon Illickal (b) (4)	30 Sep 2020 18:35:31 30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:49:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' answered with 'solicited injection reaction post injection on 28Aug2020' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:58:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:49:13
DataPoint Un-verified.	Brandon Illickal (b) (4)	03 Mar 2021 00:31:13
User entered 'pain at injection site, headache' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:31:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:58:44

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'DID NOT MEET THE AE CRITERIA' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:39:32
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.	(b) (4), (b) (6)	12 Nov 2020 08:58:57
' (Site from DM). User entered 'injection site pain'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '800'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Mar 2021 00:31:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	03 Mar 2021 00:31:13
DataPoint Un-verified.	Brandon Illickal (b) (4)	03 Mar 2021 00:31:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:31:13
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	03 Mar 2021 00:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once (ONCE)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '31 Aug 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '02 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:32:43
DataPoint Un-verified.	Brandon Illickal (b) (4)	03 Mar 2021 00:30:51
User entered '01 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:30:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '31 Aug 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:04

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User entered '1'	System	03 Mar 2021 00:31:13
User entered empty.	System	30 Sep 2020 18:35:04

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User entered '1'	System	03 Mar 2021 00:31:13
User entered empty.	System	30 Sep 2020 18:35:04

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:09
User entered '804 (804)'	System	03 Mar 2021 00:31:13
User entered empty.	System	30 Sep 2020 18:35:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 00:52:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	03 Mar 2021 00:52:52
Data point term sent to Coder Coding entries removed.	System Brandon Illickal (b) (4)	03 Mar 2021 00:38:22 03 Mar 2021 00:37:51
Data point term sent to Coder DataPoint activated with code reason code Data required.	System Brandon Illickal (b) (4)	03 Mar 2021 00:37:20 03 Mar 2021 00:37:06
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System Brandon Illickal (b) (4)	03 Mar 2021 00:33:16 03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 18:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	30 Sep 2020 18:37:52
Data point term sent to Coder	System	30 Sep 2020 18:36:32

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ibuprofen'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:50:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' answered with 'solicited injection reaction post injection; did not meet AE reporting criteria; injection was on 22sep2020' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:58:47



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE, HEADACHE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE, HEADACHE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:50:16
	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
User entered 'pain at injection site, HEADACHE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:58:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'DID NOT MEET THE AE CRITERIA' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:39:52
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:00:11
User entered 'headache'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '800'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once (ONCE)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
DataPoint Un-verified.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
User entered '24 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '2 Sep 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
DataPoint Un-verified.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
User entered '24 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	03 Mar 2021 00:37:51
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '2 Sep 2020'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
User entered empty.	System	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
User entered empty.	System	30 Sep 2020 18:35:38



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:21
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	03 Mar 2021 00:37:06
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	03 Mar 2021 00:32:58
User entered empty.	System	30 Sep 2020 18:35:38

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:57:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:57:40
Data point term sent to Coder	System	20 Oct 2020 20:56:44
User entered 'ACYCLOVIR'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'HERPES SIMPLEX'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '800'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Mar 1951'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:56:31

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:56:31



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 20:56:31

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 20:56:31

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 20:56:31

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Jan 2021 09:58:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:58:49
Data point term sent to Coder	System	14 Jan 2021 23:25:14
Coding entries removed.	Brandon Illickal (b) (4)	14 Jan 2021 23:25:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:53:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:53:29
Data point term sent to Coder	System	20 Oct 2020 21:06:02
User entered 'POTASSIUM CL'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 20:09:17
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:25:20
DataPoint Un-verified.	Brandon Illickal (b) (4)	14 Jan 2021 23:25:11
User entered 'hypertension' reason for change: Data Entry Error	Brandon Illickal (b) (4)	14 Jan 2021 23:25:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:25:55
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'POTASSIUM REPLACEMENT'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '10'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'meQ'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Jan 2020'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:05:16

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:05:16

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:05:16

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:05:16

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Jan 2021 23:10:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:10:58
Data point term sent to Coder	System	14 Jan 2021 23:10:01
Coding entries removed.	Brandon Illickal (b) (4)	14 Jan 2021 23:09:14
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:07:45
Data point term sent to Coder	System	20 Oct 2020 21:07:07
User entered 'FUROSEMIDE'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 20:09:22
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:09:23
DataPoint Un-verified.	Brandon Illickal (b) (4)	14 Jan 2021 23:09:14
User entered 'hypertension' reason for change: Data Entry Error	Brandon Illickal (b) (4)	14 Jan 2021 23:09:14
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:26:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'FLUID RETENTION'	(b) (4), (b) (6)	20 Oct 2020 21:07:04



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '20'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:24:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Jan 2020'	(b) (4), (b) (6)	20 Oct 2020 21:07:04



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:07:04

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:07:04

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:07:04

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:07:04

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
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: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:10:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:10:22
Data point term sent to Coder	System	20 Oct 2020 21:09:12
User entered 'BENAZEPRIL'	(b) (4), (b) (6)	20 Oct 2020 21:08:33



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'HYPERTENSION'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '40'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:33

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:08:33



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Jan 2010'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:27:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:27:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 21:27:11
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:08:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:08:33

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:08:33

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:08:33



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:08:33

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:04:27
Data point term sent to Coder	System	20 Oct 2020 21:11:19
User entered 'METHOCARBAMOL'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:09:34
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:20:52
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:27:27
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'LUMBAR BACK PAIN'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '500'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Aug 2017'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:11:05



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:11:05

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:11:05

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:11:05

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:14:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:14:26
Data point term sent to Coder	System	20 Oct 2020 21:13:25
User entered 'PREGABALIN'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'FIBROMYALGIA'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '100'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Aug 2019'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:13:11

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:13:11

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:13:11

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:13:11

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:16:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:16:32
Data point term sent to Coder	System	20 Oct 2020 21:15:29
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:10:09
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:23:51
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:27:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'ACID REFLUX'	(b) (4), (b) (6)	20 Oct 2020 21:14:49



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '40'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'UN Aug 2015' reason for change: Data Entry Error	Brandon Illickal (b) (4)	14 Jan 2021 23:24:56
DataPoint Un-verified.	Brandon Illickal (b) (4)	14 Jan 2021 23:23:44
User entered 'UN Aug 2019' reason for change: Data Entry Error	Brandon Illickal (b) (4)	14 Jan 2021 23:23:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Aug 2015'	(b) (4), (b) (6)	20 Oct 2020 21:14:49



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:14:49

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:14:49

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:14:49

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:14:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:20:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:20:23
Data point term sent to Coder	System	20 Oct 2020 21:19:32
User entered 'GABAPENTIN'	(b) (4), (b) (6)	20 Oct 2020 21:19:29



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'NEUROPATHY'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '300'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Jun 1982'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:19:29

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:19:29

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:19:29



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:19:29

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Per MM: Please clarify Name of Medication' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:09:28
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: ERGOCALCIFEROL, PRODUCTSYNONYM: VITAMIN D2 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:21:46
Data point term sent to Coder	System	16 Nov 2020 20:21:03
Query 'Per MM: Please clarify Name of Medication' answered with 'updated' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 20:20:26
Coding entries removed.	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 20:20:17
User entered 'VITAMIN D2' reason for change: Data Entry Error	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 20:20:17
User opened query 'Per MM: Please clarify Name of Medication' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:04:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:37:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:37:17
Data point term sent to Coder	System	20 Oct 2020 21:24:40
User entered 'VITAMINE DZ'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'ANEMIA'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '50000'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'IU (IU)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Jul 2018'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:23:52



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:23:52

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:23:52

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:23:52

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 21:26:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 21:26:24
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 21:25:41
User entered 'IBUPROFEN'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 13:44:23
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Feb 2021 01:14:11
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:28:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:25:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:25:23
User entered 'KNEE PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 21:25:23
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:24:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '800'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:24:57

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:24:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'UN Aug 2005'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:24:57

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:24:57

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:24:57

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:24:57

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:09:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:09:29
Data point term sent to Coder	System	26 Oct 2020 19:26:51
User entered 'Toradol'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 13:45:07
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Feb 2021 01:14:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:28:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Knee Pain'	(b) (4), (b) (6)	26 Oct 2020 19:26:03



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '50'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:24:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '23 Sep 2020'	(b) (4), (b) (6)	26 Oct 2020 19:26:03



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:56:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 15:56:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 15:56:33
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:26:03
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:57
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	03 Nov 2020 15:56:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 15:56:55
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	03 Nov 2020 15:56:33
User entered '01 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:49:57
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 19:26:03

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:26:03

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:26:03

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:26:03

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: METOCLOPRAMIDE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 23:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 23:57:43
Data point term sent to Coder	System	09 Mar 2021 23:56:13
User entered 'metoclopramide HCl'	Brandon Illickal (b) (4)  	09 Mar 2021 23:55:49



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'small bowel obstruction'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '10'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'mg (mg)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'four times daily (QID)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '27 Dec 2020'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '0'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '30 Dec 2020'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User entered '4'	System	09 Mar 2021 23:55:49

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User entered '1'	System	09 Mar 2021 23:55:49



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:50
User entered '804 (804)'	System	09 Mar 2021 23:55:49

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:54:44
Data point term sent to Coder	System	09 Mar 2021 23:57:13
User entered 'zofran [odansetron]'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'nausea, secondary to small bowel obstruction'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '4'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'mg (mg)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'three times daily (TID)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered empty.	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '27 Dec 2020'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '0'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered '30 Dec 2020'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:49:38
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Mar 2021 23:57:01



**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:24:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User entered '3'	System	09 Mar 2021 23:57:01

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User entered '1'	System	09 Mar 2021 23:57:01

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:55
User entered '804 (804)'	System	09 Mar 2021 23:57:01

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 00:09:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 00:09:00
Data point term sent to Coder	System	22 Apr 2021 16:37:20
User entered '0.9% normal saline'	Brandon Illickal (b) (4)	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'acute kidney injury'	(b) (4) Brandon Illickal (b) (4)	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered '500'	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'mL (mL)'	(b) (4) Brandon Illickal (b) (4)	22 Apr 2021 16:36:25



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered empty.	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'as needed (PRN)'	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered empty.	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Brandon Illickal (b) (4)	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered empty.	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered '26 Feb 2021'	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered '0'	(b) (4) Brandon Illickal (b) (4)	22 Apr 2021 16:36:25

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:24:17**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'No (N)'	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	



US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered '01 Mar 2021'	(b) (4)	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
User entered 'No (N)'	(b) (4)	22 Apr 2021 16:36:25
	Brandon Illickal (b) (4)	

US3392112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User entered empty.	System	22 Apr 2021 16:36:25

**US3392112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User entered empty.	System	22 Apr 2021 16:36:25

US3392112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:24:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:02
User entered empty.	System	22 Apr 2021 16:36:25

US3392112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:24:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:11
User entered 'No (N)'	Brandon Illickal (b) (4)  	31 Aug 2020 23:05:01

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'USA-US119-2020-MRNA-1273-P301000007'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Michael'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Cotugno'	System	20 Nov 2020 16:48:34



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:43:07
User entered 'US'	System	20 Nov 2020 16:48:58

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Dec 2020 14:38:27
User entered '1'	System	20 Nov 2020 16:48:58

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'USA-US119-2020-MRNA-1273-P301000007'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Michael'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Cotugno'	System	20 Nov 2020 16:48:34

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:43:07
User entered 'US'	System	20 Nov 2020 16:48:58

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Dec 2020 14:38:27
User entered '1'	System	20 Nov 2020 16:48:58

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:43:07
User entered '20/Nov/2020 11:48'	System	20 Nov 2020 16:48:58

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 16:48:58



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'USA-US119-2020-MRNA-1273-P301000007'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'No (N)'	System	20 Nov 2020 16:48:34



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Michael'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 16:48:53
User entered 'Cotugno'	System	20 Nov 2020 16:48:34

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:43:07
User entered 'US'	System	20 Nov 2020 16:48:58

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Dec 2020 14:38:27
User entered '1'	System	20 Nov 2020 16:48:58

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:24
User entered '07/Dec/2020 06:38'	System	07 Dec 2020 14:38:27

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:24
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 14:38:27

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'USA-US119-2020-MRNA-1273-P301000014'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45



**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Michael'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Cotugno'	System	30 Dec 2020 15:38:45



**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'US'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Mar 2021 15:37:05
User entered '2'	System	07 Jan 2021 15:14:58
User entered '1'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'USA-US119-2020-MRNA-1273-P301000014'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45



**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Michael'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Cotugno'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'US'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Mar 2021 15:37:05
User entered '2'	System	07 Jan 2021 15:14:58
User entered '1'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
User entered '30/Dec/2020 15:40'	System	30 Dec 2020 15:40:21

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 15:40:21



**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'USA-US119-2020-MRNA-1273-P301000014'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Michael'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Cotugno'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'US'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Mar 2021 15:37:05
User entered '2'	System	07 Jan 2021 15:14:58
User entered '1'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
User entered '07/Jan/2021 10:14'	System	07 Jan 2021 15:14:58

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 15:14:58

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'USA-US119-2020-MRNA-1273-P301000014'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45



**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'No (N)'	System	30 Dec 2020 15:38:45

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Yes (Y)'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Michael'	System	30 Dec 2020 15:38:45

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User entered 'Cotugno'	System	30 Dec 2020 15:38:45



US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 15:15:02
User entered 'US'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Mar 2021 15:37:05
User entered '2'	System	07 Jan 2021 15:14:58
User entered '1'	System	30 Dec 2020 15:40:21

**US3392112**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:37
User entered '10/Mar/2021 07:37'	System	10 Mar 2021 15:37:05

US3392112

Folder: SAE USA-US119-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 14:47:37
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 15:37:05

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:44
User entered		
'USA-US119-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Michael'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Cotugno'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
User entered 'US'	System	21 Apr 2021 15:36:02

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 20:47:54
User entered '1'	System	21 Apr 2021 15:36:02

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:44
User entered		
'USA-US119-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Michael'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Cotugno'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
User entered 'US'	System	21 Apr 2021 15:36:02

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 20:47:54
User entered '1'	System	21 Apr 2021 15:36:02

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
User entered '21/Apr/2021 11:36'	System	21 Apr 2021 15:36:02

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 15:36:02

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:44
User entered		
'USA-US119-2021-MRNA-1273-P301000010'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Yes (Y)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'No (N)'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Michael'	System	21 Apr 2021 15:35:24

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 15:35:48
User entered 'Cotugno'	System	21 Apr 2021 15:35:24



**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:17:51

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:59:46
User entered 'US'	System	21 Apr 2021 15:36:02

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:24:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 20:47:54
User entered '1'	System	21 Apr 2021 15:36:02

**US3392112**

**Folder: SAE USA-US119-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:24:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	30 Apr 2021 17:10:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:58:13
User entered '29/Apr/2021 16:47'	System	29 Apr 2021 20:47:54

US3392112

Folder: SAE USA-US119-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:17

**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.	Michael Cotugno (b) (4)	30 Apr 2021 17:10:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:58:13
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 20:47:54