

US3032263 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:55:16

All time stamps listed in this document are displayed in GMT

US3032263

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

---

Participant ID

US3032263

---

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

---

---

US3032263

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3032263

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Date of Birth (MMM yyyy)	(b) (6)	1954
Age		65
Age Units		YEARS
Age (Derived)		66
Sex	Female	<input checked="" type="radio"/>
	Male	<input type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

US3032263

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032263

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3032263

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

---

Were any significant conditions reported?

Yes ☒  
No ☐

---

US3032263

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991



US3032263

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	ATYPICAL ENDOMETRIAL HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3032263

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032263

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3032263

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	TONSILECTOMY
Start date (dd MMM yyyy)	UN UNK 1971
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1971
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1971
Start Year (derived)	1971
Stop Month and Year (derived)	JAN 1971
Stop Year (derived)	1971

US3032263

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	TONSILITIS
Start date (dd MMM yyyy)	UN UNK 1971
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1971
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1971
Start Year (derived)	1971
Stop Month and Year (derived)	JAN 1971
Stop Year (derived)	1971

US3032263

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	HORMONE DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	
Stop Year (derived)	



US3032263

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 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)	_____

US3032263

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032263

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Condition	RHEUMATIC FEVER
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

US3032263

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:45:17

Generated On: 09 Jun 2021 14:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Height (xxx.x)	165.1 cm
Weight (xxx.x)	55.3 kg
BMI (xxx.x)	20.28761 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)	

US3032263

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3032263

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Date of assessment (dd MMM yyyy) 20 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) UN UNK 1991

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

US3032263

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

---

**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**

AUTO BODY SHOP

---

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

**No Risk Identified** False

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

US3032263

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

<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>	



US3032263

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187213

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 ☒

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Nov 2020 20:29:56

Generated On: 09 Jun 2021 14:55:16

Height	ND - Not Done
Weight	ND - Not Done

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Nov 2020 20:29:56

Generated On: 09 Jun 2021 14:55:16

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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Nov 2020 20:29:56

Generated On: 09 Jun 2021 14:55:16

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)	20 AUG 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:38
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3032263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	11:13 (24 HR)
Collection date and time (derived)	20 AUG 2020 11:13



US3032263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:57	20 AUG 2020 10:57
Nasopharyngeal Swab 2	No		

US3032263

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

20 AUG 2020 12:38

PC Open Date & Time

20 AUG 2020 12:25

PC Close Date & Time

20 AUG 2020 14:55

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**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 96.7 °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	20 AUG 2020 15:57
PC Open Date & Time	20 AUG 2020 15:50
PC Close Date & Time	21 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

---

**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

96.0 °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

21 AUG 2020 22:58

---

PC Open Date & Time

21 AUG 2020 12:00

---

PC Close Date & Time

22 AUG 2020 11:59

---

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:13

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

---

**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

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

23 AUG 2020 12:24

---

PC Open Date & Time

23 AUG 2020 12:00

---

PC Close Date & Time

24 AUG 2020 11:59

---

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

---

**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

97.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

24 AUG 2020 12:03

---

PC Open Date & Time

24 AUG 2020 12:00

---

PC Close Date & Time

25 AUG 2020 11:59

---



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 13:49

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

---

**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

97.6 °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 AUG 2020 22:36

---

PC Open Date & Time

26 AUG 2020 12:00

---

PC Close Date & Time

27 AUG 2020 11:59

---

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**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

20 AUG 2020 12:40

PC Open Date & Time

20 AUG 2020 12:25

PC Close Date & Time

20 AUG 2020 14:55

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 15:57

PC Open Date & Time

20 AUG 2020 15:50

PC Close Date & Time

21 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 22:56

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**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

22 AUG 2020 12:13

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**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

23 AUG 2020 12:24

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**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

24 AUG 2020 12:03

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 13:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 22:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**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 ☐

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 12:41
PC Open Date & Time	20 AUG 2020 12:25
PC Close Date & Time	20 AUG 2020 14:55

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**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 ☐

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 15:58
PC Open Date & Time	20 AUG 2020 15:50
PC Close Date & Time	21 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**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 ☒

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 22:57
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

56 of 3127

EAB) (1725)

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

58 of 3127

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**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 ☒

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

		Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 12:04	
PC Open Date & Time	24 AUG 2020 12:00	
PC Close Date & Time	25 AUG 2020 11:59	

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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 ☒

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 13:50
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**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 ☒

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 22:37
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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)	08:48 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 08:48
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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)	10:12 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:12
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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.*

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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) 09:41 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 09:41

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

US3032263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

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

Collection date (dd MMM yyyy)	22 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	09:08 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 SEP 2020 09:08
------------------------------------	-------------------

US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

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	09:00	22 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3032263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:55:13

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

22 SEP 2020 10:12

PC Open Date & Time

22 SEP 2020 10:01

PC Close Date & Time

22 SEP 2020 12:31

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	22 SEP 2020 14:26
PC Open Date & Time	22 SEP 2020 13:26
PC Close Date & Time	23 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 07:57

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

24 SEP 2020 12:34

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**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):

PC Time Stamp

25 SEP 2020 12:08

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**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 13:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

---

**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

96.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

27 SEP 2020 19:45

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

---

**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

97.6 °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

29 SEP 2020 08:11

---

PC Open Date & Time

28 SEP 2020 12:00

---

PC Close Date & Time

29 SEP 2020 11:59

---



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**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 10:13

PC Open Date & Time

22 SEP 2020 10:01

PC Close Date & Time

22 SEP 2020 12:31

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 14:26

PC Open Date & Time

22 SEP 2020 13:26

PC Close Date & Time

23 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 07:57

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**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 12:34

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**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 12:08

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**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 13:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**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 19:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**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

29 SEP 2020 08:12

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**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 ☐

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 10:13
PC Open Date & Time	22 SEP 2020 10:01
PC Close Date & Time	22 SEP 2020 12:31

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**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 ☐

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 14:27
PC Open Date & Time	22 SEP 2020 13:26
PC Close Date & Time	23 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**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)

100 of 3127

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 07:57
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

102 of 3127

EAB) (1725)

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:35
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**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 ☒

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:08
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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 ☒

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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 ☒

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:46
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**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)

110 of 3127

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 08:12
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59



US3032263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 22:04:00

Generated On: 09 Jun 2021 14:55:16

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*

US3032263

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 22:04:00

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:45:17

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:45:17

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

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)	17:24 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 17:24
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3032263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

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.*

US3032263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

17:40 (24 HR)

Collection date and time (derived)

19 OCT 2020 17:40

US3032263

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:58:08

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 05:57:59

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 07:54:18

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 06:20:12

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 21:17:38
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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	24 NOV 2020 08:51:14
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59



US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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

28 NOV 2020 08:06:23

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
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 type="radio"/> Yes <input checked="" type="radio"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	05 DEC 2020 08:51:08
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 DEC 2020 10:55:45
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 18:01:41

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 08:31:55
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 10:22:26

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 JAN 2021 12:01:20
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59



US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 09:15:01

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:07:05

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 00:01:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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

06 FEB 2021 09:31:16

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 00:50:15

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 20:39:08

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 14:32:54

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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

06 MAR 2021 00:05:26

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59



US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 11:18:17

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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

20 MAR 2021 08:47:08

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 08:08:04

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 08:39:43

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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

10 APR 2021 06:56:11

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 12:26:17
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

Date and time of submission

26 APR 2021 12:19:39

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

05 MAY 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

23 JUN 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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="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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

28 JUL 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

04 AUG 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

25 AUG 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

08 SEP 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

13 OCT 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

03 NOV 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

24 NOV 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

01 DEC 2021 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JAN 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 FEB 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

09 MAR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

26 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

04 MAY 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 MAY 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

01 JUN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

08 JUN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 JUN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

29 JUN 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 JUL 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

27 JUL 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 AUG 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

10 AUG 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 AUG 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
---	-------------------

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

24 AUG 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

---

[Patient Cloud Close Date & Time](#)

---

05 OCT 2022 23:59

---

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**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 ☐



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3032263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

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"/>

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3032263

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:55:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 14:33:10

US3032263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

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*

US3032263

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

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) \_\_\_\_\_

US3032263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

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.*

US3032263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)



US3032263

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3032263**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

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*

**US3032263**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

Date of Contact	4 DEC 2020
Time of Contact	15:40
Date and Time of Contact (derived)	4 DEC 2020 15:40
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

325 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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)

326 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" 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"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	5 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	6 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

333 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	36.0 C	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

337 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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)

338 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	8 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	9 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

346 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	10 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

349 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	11 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	12 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

357 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	13 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

361 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	14 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	15 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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	16 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

373 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	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 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 3127

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 15:42:37

Generated On: 09 Jun 2021 14:55:16

Date of Visit 7 DEC 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 7 DEC 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

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Apr 2021 15:42:37

Generated On: 09 Jun 2021 14:55:16

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 \_\_\_\_\_

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Apr 2021 15:42:37

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 06 Apr 2021 15:42:37

Generated On: 09 Jun 2021 14:55:16

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



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Jan 2021 19:17:55

Generated On: 09 Jun 2021 14:55:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3032263

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Dec 2020 19:48:30

Generated On: 09 Jun 2021 14:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 DEC 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 11:40
Height (xxx.x)	165.1 cm
Weight (xxx.x)	56 kg
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032263

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3032263

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 DEC 2020

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 07 Jan 2021 19:17:55

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	SICKD28

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Jan 2021 19:30:45

Generated On: 09 Jun 2021 14:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 JAN 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 09:20
Height (xxx.x)	165.1 cm
Weight (xxx.x)	50 kg
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Jan 2021 19:17:55

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 JAN 2021

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

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 07 Jan 2021 19:17:55

Generated On: 09 Jun 2021 14:55:16

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 JAN 2021

US3032263

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

Form: Visit Date

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

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

Visit date (dd MMM yyyy)	2 FEB 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3032263

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:27:39

Generated On: 09 Jun 2021 14:55:16

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

US3032263

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3032263

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	2 FEB 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 09:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	2 FEB 2021
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:12
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

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

Form: Physical Examination

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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



US3032263

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

Form: Exposure

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 10:40

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

US3032263

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 FEB 2021

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

2 FEB 2021 09:25

US3032263

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	09:29
Collection Date and Time (derived)	2 FEB 2021 09:29

US3032263

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

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:45

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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)	2 MAR 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 09:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 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)	70 mmHg
Diastolic Blood Pressure units	MMHG



US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

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)	2 MAR 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 10:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3032263

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3032263

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 MAR 2021

What was the treatment time? (00:00-23:59) 09:28 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 09:28

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

US3032263

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:04:44

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:38:32

Generated On: 09 Jun 2021 14:55:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3032263

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:38:32

Generated On: 09 Jun 2021 14:55:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032263

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3032263

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 APR 2021
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 15:00
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3032263

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

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.*

US3032263

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:42:38

Generated On: 09 Jun 2021 14:55:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 APR 2021
Collection time (00:00-23:59)	15:07 (24 HR)
Collection date and time (derived)	1 APR 2021 15:07

US3032263

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Dec 2020 19:48:29

Generated On: 09 Jun 2021 14:55:16

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	USA-US032-2021-MRNA-1273-P30 1000005
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	4 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)	17 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	12 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

419 of 3127

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

---

SUBJECT WAS SEEN FOR COVID  
SYMPTOMS ON 07DEC2020.  
SUBJECTS HEART RATE WAS  
IRREGULAR AND SLOW.  
SUBJECT WAS DIZZY AND  
LIGHT HEADED. WE REFERRED  
SUBJECT TO THE NEAREST  
EMERGENCY DEPARTMENT.  
SUBJECT WAS ADMITTED TO  
THE HOSPITAL FOR COVID-19.  
SUBJECT WAS NOTED TO HAVE  
INTERMITTENT MOBILTZ II  
HEART BLOCK.  
UPDATE 22FEB: PT HAD A  
POSITIVE COVID TEST  
COLLECTED ON 04DEC2020  
AND WAS NOTIFIED OF  
POSITIVE RESULTS 09DEC2020.  
SHE ALSO HAD A RAPID COVID  
PCR TEST PERFORMED AT THE  
ER ON 07DEC2020 WHICH WAS  
POSITIVE.

---

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

---

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	USA-US032-2021-MRNA-1273-P30 1000005
Adverse event	SECOND DEGREE MOBITZ II AV BLOCK, INTERMITTENT
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)	7 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)	08 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	7 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	12 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	422 of 3127

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Number of Days in ICU	5
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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	



US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

---

SUBJECT WAS HOSPITALIZED  
WITH COVID-19 AND  
SUBSEQUENTLY WAS FOUND  
TO HAVE A HEART BLOCK  
WHICH PROLONGED HER  
CURRENT HOSPITALIZATION.  
UPDATE 22FEB2021: THE  
SUBJECT HAD A PERMANENT  
PACEMAKER PLACED ON  
08JAN2021 WHICH RESOLVED  
THE MOBITZ II HEART BLOCK

---

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

---

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	
Adverse event	VIRAL PNEUMONIA
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	07 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)	17 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

425 of 3127

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	
Adverse event	ANXIETY
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)	07 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)	17 DEC 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	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	
Adverse event	HYPOMAGNESEMIA
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)	09 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)	09 DEC 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)

429 of 3127

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

AEID	
Adverse event	MITRAL REGURGITATION
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)	08 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)	08 JAN 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 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)

431 of 3127



US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:55:12

Generated On: 09 Jun 2021 14:55:16

---

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

Yes ☒

No ☐

---

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

---

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication ACUTE EXACERBATION OF  
CHRONIC OBSTRUCTIVE  
AIRWAY DISEASE

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

434 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ACUTE EXACERBATION OF  
CHRONIC OBSTRUCTIVE  
AIRWAY DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

436 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY:  
HYPOTHYROIDISM

Dose per administration .088

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)

438 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication ESTRADIOL

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: HORMONE  
REPLACEMENT

Dose per administration .05

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

TWICE WEEKLY

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

440 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1991	
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"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

442 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: ACID  
REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

444 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SUSPECTED COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

446 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SUSPECTED COVID-19

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

448 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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) 4 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SUSPECTED COVID-19

Dose per administration 250

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

450 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 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)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication CONVALESCENT PLASMA

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

452 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 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) 07 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication REMDESIVIR

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 700

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)

454 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	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 checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
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"/>	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

456 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

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

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication SECOND DEGREE MOBILTZ II  
BLOCK

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

458 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	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)	7 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)		11 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication ELIQUIS

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOT PREVENTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

460 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	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)	8 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

462 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 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)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 600

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

464 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 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)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

466 of 3127

EAB) (1725)

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	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)		09 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)		09 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR  
HYPOKALEMIA ASSOCIATED  
WITH FUROSEMIDE USE

Dose per administration 40

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

468 of 3127

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 16:17:41

Generated On: 09 Jun 2021 14:55:16

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Feb 2021 19:41:54

Generated On: 09 Jun 2021 14:55:16

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 16:17:42

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 JAN 2021	PERMANENT PACEMAKER PLACEMENT	Adverse Event	
04 DEC 2020	SARS-COV-2 PCR	Adverse Event	
07 DEC 2020	COMPREHENSIVE METABOLIC PANEL	Adverse Event	
07 DEC 2020	D-DIMER	Adverse Event	
07 DEC 2020	TROPONIN	Adverse Event	
07 DEC 2020	COMPLETE BLOOD COUNT	Adverse Event	
08 DEC 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
07 DEC 2020	CHEST X-RAY	Adverse Event	
07 DEC 2020	CREATINE KINASE	Adverse Event	
08 DEC 2020	PROCALCITONIN	Adverse Event	
07 DEC 2020	SARS-COV-2 ANTIGEN TEST	Adverse Event	



US3032263

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:55:16

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 ☐

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/FEB/2021 20:07
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

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/FEB/2021 13:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/FEB/2021 12:02
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

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/FEB/2021 12:40
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

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:55
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

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/MAR/2021 12:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 18:24:03

Generated On: 09 Jun 2021 14:55:16

SAEID	USA-US032-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 11:51
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

US3032263 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

**US3032263**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:55:16**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:16:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'US3032263'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:52

US3032263

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:30:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:23:22
	(b) (4)	

US3032263

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:30:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:53

US3032263

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:30:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:23:22

**US3032263**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'SCRN'	System	26 Aug 2020 18:23:22

US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:54



US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '65'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'YEARS'	System	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '66'	System	20 Aug 2020 17:09:41

US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Female (F)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'l'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09



**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

**US3032263**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:16**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

US3032263

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:16

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:09

US3032263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'Aug 2020'	System	20 Aug 2020 17:09:41



**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2020'	System	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Amendment 2 (2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

US3032263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:16**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:41

US3032263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:53

US3032263

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'I'	System	20 Aug 2020 17:09:41



US3032263

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:29

**US3032263**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:55:16**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:24

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:02:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:02:32
Data point term sent to Coder	System	26 Aug 2020 18:32:43
User entered 'Hysterectomy'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:31:47



US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:31:47

**US3032263**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:31:47

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometrial hyperplasia, LLT: Atypical hyperplasia of endometrium - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:16
Data point term sent to Coder	System	26 Aug 2020 18:32:45
User entered 'atypical endometrial hyperplasia'	Linden DeBoer (b) (4)	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'UN UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered 'No (N)'	Linden DeBoer (b) (4)	26 Aug 2020 18:32:41
	(b) (4)	



US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered 'UN UNK 1991'	Linden DeBoer (b) (4)	26 Aug 2020 18:32:41
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:32:41

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:02:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:02:44
Data point term sent to Coder	System	26 Aug 2020 18:33:48
User entered 'Anxiety'	Linden DeBoer (b) (4)	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2017'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:10



US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2017'	System	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2017'	System	26 Aug 2020 18:33:10

US3032263

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:33:10

**US3032263**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:33:10



US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
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.' (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.' answered with 'con meds have been added' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 07:15:57
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4)	22 Sep 2020 15:28:41
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	(b) (4), (b) (6)	10 Sep 2020 08:43:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:02:46
Data point term sent to Coder	(b) (4)	27 Aug 2020 18:02:46
User entered 'hypothyroidism'	System Linden DeBoer (b) (4)	26 Aug 2020 18:33:50 26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2005'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2005'	System	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2005'	System	26 Aug 2020 18:33:32



US3032263

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:33:32

**US3032263**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:33:32

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
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.' (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.' answered with 'con meds have been added' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 07:16:36
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:28:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive airways disease - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:05
Data point term sent to Coder	System	26 Aug 2020 18:34:53
User entered 'acute exacerbation of chronic obstructive airway disease'	Linden DeBoer (b) (4)	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:56
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	24 Nov 2020 20:09:10
	(b) (4)	
User entered 'UN UNK 2019' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 20:09:10
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
	(b) (4)	
Signature has been broken.	Russell Herstein (b) (4)	21 Oct 2020 02:18:16
	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	Russell Herstein (b) (4)	21 Oct 2020 02:18:16
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered 'un UNK 2019'	Linden DeBoer (b) (4)	26 Aug 2020 18:34:07
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:34:07



US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2019'	System	24 Nov 2020 20:09:10
User entered 'Jan 2018'	System	21 Oct 2020 02:18:16
User entered 'Jan 2019'	System	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2019'	System	24 Nov 2020 20:09:10
User entered '2018'	System	21 Oct 2020 02:18:16
User entered '2019'	System	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:34:07

**US3032263**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:34:07

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:56
User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	24 Nov 2020 20:10:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:10:59
Data point term sent to Coder	System	24 Nov 2020 20:10:14
Coding entries removed.	Linden DeBoer (b) (4)	24 Nov 2020 20:09:27
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 20:09:27
User entered 'COLONOSCoPY' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 20:09:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:14:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:14:50
Data point term sent to Coder	System	26 Aug 2020 18:35:56
User entered 'colonoscopy'	Linden DeBoer (b) (4)	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2014'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:35



US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2014'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2014'	System	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2014'	System	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2014'	System	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2014'	System	26 Aug 2020 18:35:35

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:04:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:04:04
Data point term sent to Coder	System	26 Aug 2020 18:36:57
User entered 'tonsilectomy'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1971'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59



US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1971'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1971'	System	26 Aug 2020 18:35:59

**US3032263**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1971'	System	26 Aug 2020 18:35:59

US3032263

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1971'	System	26 Aug 2020 18:35:59

**US3032263**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1971'	System	26 Aug 2020 18:35:59



US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	27 Aug 2020 18:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:04:02
Data point term sent to Coder	System	26 Aug 2020 18:36:57
User entered 'tonsillitis'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1971'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '0'	Linden DeBoer (b) (4)	26 Aug 2020 18:36:18
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1971'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1971'	System	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1971'	System	26 Aug 2020 18:36:18



US3032263

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1971'	System	26 Aug 2020 18:36:18

**US3032263**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1971'	System	26 Aug 2020 18:36:18

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Investigations, HLG: Endocrine investigations (incl sex hormones), HLT: Endocrine analyses and imaging NEC, PT: Hormone level abnormal, LLT: Hormone level abnormal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:04:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:04:03
Data point term sent to Coder	System	26 Aug 2020 18:36:57
User entered 'hormone deficiency'	Linden DeBoer (b) (4)	26 Aug 2020 18:36:47
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:36:47



US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:36:47

**US3032263**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:55:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:36:47

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as SOC: Gastrointestinal disorders, HLG: 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)	27 Aug 2020 18:04:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:04:18
Data point term sent to Coder	System	26 Aug 2020 18:38:00
User entered 'acid reflux'	Linden DeBoer (b) (4)	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2010'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:37:04



US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:37:04

**US3032263**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 2010'	System	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '2010'	System	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:55:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:37:04

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User closed query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM). User signature succeeded.		30 Sep 2020 11:28:12
	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
Query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' answered with 'subject is both, both this and surgery occurred same year' (Site from DM).	Kelsey Kelley (b) (4)	22 Sep 2020 15:31:45
	(b) (4)	
User opened query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:45:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:04:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:04:30
	(b) (4)	
Data point term sent to Coder	System	26 Aug 2020 18:39:01
User entered 'postmenopausal'	Linden DeBoer (b) (4)	26 Aug 2020 18:38:03
	(b) (4)	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

614 of 3127

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:03



US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:03

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:03

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:03

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:32:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:03

**US3032263**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1991'	System	26 Aug 2020 18:38:03

US3032263

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1991'	System	26 Aug 2020 18:38:03

**US3032263**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:38:03

**US3032263**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:55:16**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered empty.	System	26 Aug 2020 18:38:03



US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.	(b) (4)	30 Apr 2021 14:23:17
Data hard unlocked.	(b) (4)	30 Apr 2021 04:46:53
Data hard locked.	(b) (4)	28 Apr 2021 18:55:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Rheumatic fever, LLT: Rheumatic fever - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:45:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:45:00
Data point term sent to Coder	System	23 Apr 2021 21:44:18
User entered 'rheumatic fever'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	26 Aug 2020 18:38:19

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.		30 Apr 2021 14:23:17
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'un UNK 1960'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:19

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4) (u) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.		30 Apr 2021 14:23:17
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:38:19
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.		30 Apr 2021 14:23:17
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'No (N)'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:19

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.	(b) (4)	30 Apr 2021 14:23:17
Data hard unlocked.	(b) (4)	30 Apr 2021 04:46:53
Data hard locked.	(b) (4)	28 Apr 2021 18:55:41
User entered 'un UNK 1960'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:19

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 18:13:14
DataPoint Verified.		30 Apr 2021 14:23:17
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:38:19

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1960'	System	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:38:19
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1960'	System	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:38:19
	(b) (4)	



US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered 'Jan 1960'	System	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:38:19
	(b) (4)	

US3032263

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:55:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:43:16
Data hard unlocked.		03 May 2021 20:38:33
Data hard locked.		01 May 2021 18:13:14
Data hard unlocked.		30 Apr 2021 04:46:53
Data hard locked.		28 Apr 2021 18:55:41
User entered '1960'	System	23 Apr 2021 21:43:45
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	23 Apr 2021 21:43:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:38:19
	(b) (4)	

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:23

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '10:15'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:23

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '20 Aug 2020 10:15'	System	26 Aug 2020 18:39:23

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '165.1' cm	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:09:41

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '55.3' kg	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:09:41



**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
Amendment Manager: User entered '20.28761'	System	17 Sep 2020 00:16:05
User entered '20.3'	System	26 Aug 2020 18:39:23
DataPoint set to visible.	System	20 Aug 2020 17:09:41

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'kg/m2'	System	26 Aug 2020 18:39:23
DataPoint set to visible.	System	20 Aug 2020 17:09:41

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:12:46
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:10:26
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:10:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:10:20
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:16:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:55:13
User entered '36.5' C	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:23

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered 'Oral (Oral)'	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '70'	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'bpm'	System	26 Aug 2020 18:39:23

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '17'	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	



**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'breaths/min'	System	26 Aug 2020 18:39:23

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '123'	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	26 Aug 2020 18:39:23

US3032263

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:10:20
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '72'	Linden DeBoer (b) (4)	26 Aug 2020 18:39:23
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	26 Aug 2020 18:39:23

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41

**US3032263**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41

**US3032263**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:55:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:36



**US3032263**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:55:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:36

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57

US3032263

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:55:16

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:39:57

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:39:57
	(b) (4)	

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57

**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57



**US3032263**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:55:16**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:39:57

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:40:54
	(b) (4)	

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54



US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	26 Aug 2020 18:40:54
	(b) (4)	

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:40:54
	(b) (4)	

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Auto Body Shop'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	Linden DeBoer (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54



US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'l'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	Linden DeBoer (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		17 Dec 2020 19:33:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:40:54

US3032263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:10

US3032263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:10



US3032263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

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 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:10

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'VISIT1'	System	26 Aug 2020 18:41:10

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:35:04

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:52:36
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:52:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:35:04
User entered '187213' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:35:04

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:35:04

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

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 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:37

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

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 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:37

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:37



US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:41:37

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:41:37
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:15:28
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:36:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:44:49

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:48:34
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:24:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:55:13
User entered '165.1' cm	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '55.3' kg	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:48:34
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:24:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:55:13
User entered '165.1' cm	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '55.3' kg	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54



US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '10:15'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered '20 Aug 2020 10:15'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '36.5' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '70'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54



US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'bpm'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '17'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'breaths/min'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '123'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'mmHg'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '72'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'mmHg'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 03:48:34
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Oct 2020 14:19:07
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:24:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:55:13
User entered '165.1' cm	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54



US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:39:14
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	13 Oct 2020 14:19:07
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '55.3' kg	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:56
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	24 Nov 2020 20:07:55
	(b) (4)	
User entered '12:38' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 20:07:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '13:38'	Linden DeBoer (b) (4)	26 Aug 2020 18:43:54
	(b) (4)	

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered '20 Aug 2020 12:38'	System	24 Nov 2020 20:07:55
User entered '20 Aug 2020 13:38'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '36.5' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54



US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '58'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'bpm'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '15'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'breaths/min'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '136'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'mmHg'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '84'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:43:54



US3032263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'mmHg'	System	26 Aug 2020 18:43:54

US3032263

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:01

US3032263

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:33:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:01

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

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 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58



US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '12:05'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:09
User entered 'ONCE'	System	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:09:58

US3032263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:24

US3032263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:24

US3032263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '11:13'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:24



**US3032263**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered '20 Aug 2020 11:13'	System	26 Aug 2020 18:44:24

US3032263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45

US3032263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '10:57'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered '20 Aug 2020 10:57'	System	26 Aug 2020 18:44:45

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45

US3032263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:45



**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:16**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	26 Aug 2020 18:44:45
	(b) (4)	

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered empty.	System	26 Aug 2020 18:44:45

US3032263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:34:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	26 Aug 2020 18:44:48

**US3032263**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'I'	System	26 Aug 2020 18:44:48

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:37:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b4781973-8996-4693-8fb1-9015548d612a'	System	20 Aug 2020 17:38:53
User entered 'Yes (Y)'	System	20 Aug 2020 17:38:53

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:38:29', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b4781973-8996-4693-8fb1-9015548d612a'	System	20 Aug 2020 17:38:53
User entered '97.5'	System	20 Aug 2020 17:38:53

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:38:37', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b4781973-8996-4693-8fb1-9015548d612a'	System	20 Aug 2020 17:38:53
User entered 'No (N)'	System	20 Aug 2020 17:38:53



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:38:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b4781973-8996-4693-8fb1-9015548d612a' User entered '20 Aug 2020 12:38'	System	20 Aug 2020 17:38:53
	System	20 Aug 2020 17:38:53

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 12:25'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 14:55'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:56:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '28123d08-4aa7-44a0-8c9b-152b18f722d6' User entered 'Yes (Y)'	System	20 Aug 2020 20:57:15
	System	20 Aug 2020 20:57:15

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:56:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '28123d08-4aa7-44a0-8c9b-152b18f722d6' User entered '96.7'	System	20 Aug 2020 20:57:15
	System	20 Aug 2020 20:57:15

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '28123d08-4aa7-44a0-8c9b-152b18f722d6' User entered 'No (N)'	System	20 Aug 2020 20:57:15
	System	20 Aug 2020 20:57:15

**US3032263**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '28123d08-4aa7-44a0-8c9b-152b18f722d6' User entered '20 Aug 2020 15:57'	System	20 Aug 2020 20:57:15
	System	20 Aug 2020 20:57:15



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 15:50'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 2'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:57:34', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a68dc835-fcdd-4104-a2eb-de4ccd8c5f54'	System	22 Aug 2020 03:58:10
User entered 'Yes (Y)'	System	22 Aug 2020 03:58:10

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:57:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a68dc835-fcdd-4104-a2eb-de4ccd8c5f54' User entered '96.0'	System	22 Aug 2020 03:58:10
	System	22 Aug 2020 03:58:10

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:58:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a68dc835-fcdd-4104-a2eb-de4ccd8c5f54'	System	22 Aug 2020 03:58:10
User entered 'No (N)'	System	22 Aug 2020 03:58:10

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:58:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a68dc835-fcdd-4104-a2eb-de4ccd8c5f54'	System	22 Aug 2020 03:58:10
User entered '21 Aug 2020 22:58'	System	22 Aug 2020 03:58:10

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:09:58



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 3'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:12:54', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3087ab61-6ab4-458d-839d-0490cbe7d925'	System	22 Aug 2020 17:13:15
User entered 'Yes (Y)'	System	22 Aug 2020 17:13:15

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3087ab61-6ab4-458d-839d-0490cbe7d925'	System	22 Aug 2020 17:13:15
User entered '97.9'	System	22 Aug 2020 17:13:15

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3087ab61-6ab4-458d-839d-0490cbe7d925'	System	22 Aug 2020 17:13:15
User entered 'No (N)'	System	22 Aug 2020 17:13:15

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3087ab61-6ab4-458d-839d-0490cbe7d925'	System	22 Aug 2020 17:13:15
User entered '22 Aug 2020 12:13'	System	22 Aug 2020 17:13:15

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:09:58



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 4'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5b405708-2ca2-4d7b-86b2-b57599d6340f' User entered 'Yes (Y)'	System	23 Aug 2020 17:24:34
	System	23 Aug 2020 17:24:34

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:24', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5b405708-2ca2-4d7b-86b2-b57599d6340f' User entered '97.9'	System	23 Aug 2020 17:24:34
	System	23 Aug 2020 17:24:34

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5b405708-2ca2-4d7b-86b2-b57599d6340f' User entered 'No (N)'	System	23 Aug 2020 17:24:34
	System	23 Aug 2020 17:24:34

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5b405708-2ca2-4d7b-86b2-b57599d6340f' User entered '23 Aug 2020 12:24'	System	23 Aug 2020 17:24:34
	System	23 Aug 2020 17:24:34

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 5'	System	20 Aug 2020 17:09:58



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6f14e413-ef08-4acb-a880-1f417062bc3e' User entered 'Yes (Y)'	System	24 Aug 2020 17:03:38
	System	24 Aug 2020 17:03:38

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:25', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6f14e413-ef08-4acb-a880-1f417062bc3e' User entered '97.8'	System	24 Aug 2020 17:03:38
	System	24 Aug 2020 17:03:38

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:29', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6f14e413-ef08-4acb-a880-1f417062bc3e' User entered 'No (N)'	System	24 Aug 2020 17:03:38
	System	24 Aug 2020 17:03:38

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:33', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6f14e413-ef08-4acb-a880-1f417062bc3e' User entered '24 Aug 2020 12:03'	System	24 Aug 2020 17:03:38
	System	24 Aug 2020 17:03:38

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 6'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:21', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '90994acb-c2db-4486-a3a8-214eb4dcdf43' User entered 'Yes (Y)'	System	25 Aug 2020 18:49:47
	System	25 Aug 2020 18:49:47



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '90994acb-c2db-4486-a3a8-214eb4dcdf43' User entered '97.9'	System	25 Aug 2020 18:49:47
	System	25 Aug 2020 18:49:47

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '90994acb-c2db-4486-a3a8-214eb4dcdf43'	System	25 Aug 2020 18:49:47
User entered 'No (N)'	System	25 Aug 2020 18:49:47

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:43', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '90994acb-c2db-4486-a3a8-214eb4dcdf43' User entered '25 Aug 2020 13:49'	System	25 Aug 2020 18:49:47
	System	25 Aug 2020 18:49:47

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 7'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:35:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '805b454b-4be7-4615-96b9-1ec71c0bc9a3' User entered 'Yes (Y)'	System	27 Aug 2020 03:36:08
	System	27 Aug 2020 03:36:08

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:35:58', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '805b454b-4be7-4615-96b9-1ec71c0bc9a3' User entered '97.6'	System	27 Aug 2020 03:36:08
	System	27 Aug 2020 03:36:08



US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '805b454b-4be7-4615-96b9-1ec71c0bc9a3'	System	27 Aug 2020 03:36:08
User entered 'No (N)'	System	27 Aug 2020 03:36:08

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '805b454b-4be7-4615-96b9-1ec71c0bc9a3'	System	27 Aug 2020 03:36:08
User entered '26 Aug 2020 22:36'	System	27 Aug 2020 03:36:08

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:39:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7708678d-2108-4e4f-886f-cf6e957dd76c'	System	20 Aug 2020 17:40:21
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 17:40:21

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:39:30', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7708678d-2108-4e4f-886f-cf6e957dd76c' User entered 'No (N)'	System	20 Aug 2020 17:40:21
	System	20 Aug 2020 17:40:21

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:39:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7708678d-2108-4e4f-886f-cf6e957dd76c'	System	20 Aug 2020 17:40:21
User entered 'No (N)'	System	20 Aug 2020 17:40:21



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7708678d-2108-4e4f-886f-cf6e957dd76c' User entered 'None (1)'	System	20 Aug 2020 17:40:21
	System	20 Aug 2020 17:40:21

**US3032263**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7708678d-2108-4e4f-886f-cf6e957dd76c' User entered '20 Aug 2020 12:40'	System	20 Aug 2020 17:40:21
	System	20 Aug 2020 17:40:21

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 12:25'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 14:55'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '95451a4f-0292-4dd1-a16b-76ca0176d6d7'	System	20 Aug 2020 20:57:37
User entered 'None (1)'	System	20 Aug 2020 20:57:37

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:21', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '95451a4f-0292-4dd1-a16b-76ca0176d6d7' User entered 'No (N)'	System	20 Aug 2020 20:57:37
	System	20 Aug 2020 20:57:37

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '95451a4f-0292-4dd1-a16b-76ca0176d6d7' User entered 'No (N)'	System	20 Aug 2020 20:57:37
	System	20 Aug 2020 20:57:37



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:30', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '95451a4f-0292-4dd1-a16b-76ca0176d6d7' User entered 'None (1)'	System	20 Aug 2020 20:57:37
	System	20 Aug 2020 20:57:37

**US3032263**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:34', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '95451a4f-0292-4dd1-a16b-76ca0176d6d7' User entered '20 Aug 2020 15:57'	System	20 Aug 2020 20:57:37
	System	20 Aug 2020 20:57:37

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 15:50'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 2'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:55:58', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f6a23d89-f0e7-4fc3-b15b-e4b3c0e435a0'	System	22 Aug 2020 03:56:26
User entered 'None (1)'	System	22 Aug 2020 03:56:26

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:04', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f6a23d89-f0e7-4fc3-b15b-e4b3c0e435a0'	System	22 Aug 2020 03:56:26
User entered 'No (N)'	System	22 Aug 2020 03:56:26

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f6a23d89-f0e7-4fc3-b15b-e4b3c0e435a0' User entered 'No (N)'	System	22 Aug 2020 03:56:26
	System	22 Aug 2020 03:56:26



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:15', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f6a23d89-f0e7-4fc3-b15b-e4b3c0e435a0'	System	22 Aug 2020 03:56:26
User entered 'None (1)'	System	22 Aug 2020 03:56:26

**US3032263**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f6a23d89-f0e7-4fc3-b15b-e4b3c0e435a0'	System	22 Aug 2020 03:56:26
User entered '21 Aug 2020 22:56'	System	22 Aug 2020 03:56:26

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 3'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:21', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c6e46a8b-7c3c-4454-af17-c8deaa62f907'	System	22 Aug 2020 17:13:39
User entered 'None (1)'	System	22 Aug 2020 17:13:39

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:25', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c6e46a8b-7c3c-4454-af17-c8deaa62f907'	System	22 Aug 2020 17:13:39
User entered 'No (N)'	System	22 Aug 2020 17:13:39

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c6e46a8b-7c3c-4454-af17-c8deaa62f907'	System	22 Aug 2020 17:13:39
User entered 'No (N)'	System	22 Aug 2020 17:13:39



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c6e46a8b-7c3c-4454-af17-c8deaa62f907'	System	22 Aug 2020 17:13:39
User entered 'None (1)'	System	22 Aug 2020 17:13:39

**US3032263**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c6e46a8b-7c3c-4454-af17-c8deaa62f907' User entered '22 Aug 2020 12:13'	System	22 Aug 2020 17:13:39
	System	22 Aug 2020 17:13:39

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 4'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6fc8e24d-4c9a-4138-b7e4-1b36f1495430' User entered 'None (1)'	System	23 Aug 2020 17:24:54
	System	23 Aug 2020 17:24:54

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:43', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6fc8e24d-4c9a-4138-b7e4-1b36f1495430' User entered 'No (N)'	System	23 Aug 2020 17:24:54
	System	23 Aug 2020 17:24:54

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:46', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6fc8e24d-4c9a-4138-b7e4-1b36f1495430' User entered 'No (N)'	System	23 Aug 2020 17:24:54
	System	23 Aug 2020 17:24:54



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6fc8e24d-4c9a-4138-b7e4-1b36f1495430' User entered 'None (1)'	System	23 Aug 2020 17:24:54
	System	23 Aug 2020 17:24:54

**US3032263**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6fc8e24d-4c9a-4138-b7e4-1b36f1495430' User entered '23 Aug 2020 12:24'	System	23 Aug 2020 17:24:54
	System	23 Aug 2020 17:24:54

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 5'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ffb077f8-8834-4014-bb93-aca584f004da'	System	24 Aug 2020 17:04:03
User entered 'None (1)'	System	24 Aug 2020 17:04:03

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:41', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ffb077f8-8834-4014-bb93-aca584f004da' User entered 'No (N)'	System	24 Aug 2020 17:04:03
	System	24 Aug 2020 17:04:03

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:46', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ffb077f8-8834-4014-bb93-aca584f004da' User entered 'No (N)'	System	24 Aug 2020 17:04:03
	System	24 Aug 2020 17:04:03



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ffb077f8-8834-4014-bb93-aca584f004da' User entered 'None (1)'	System	24 Aug 2020 17:04:03
	System	24 Aug 2020 17:04:03

**US3032263**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:03:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ffb077f8-8834-4014-bb93-aca584f004da' User entered '24 Aug 2020 12:03'	System	24 Aug 2020 17:04:03
	System	24 Aug 2020 17:04:03

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 6'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:48', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ba1e251f-247a-4ae8-8051-ee6e7d6cfcff'	System	25 Aug 2020 18:50:23
User entered 'None (1)'	System	25 Aug 2020 18:50:23

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:52', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ba1e251f-247a-4ae8-8051-ee6e7d6cfcff'	System	25 Aug 2020 18:50:23
User entered 'No (N)'	System	25 Aug 2020 18:50:23

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ba1e251f-247a-4ae8-8051-ee6e7d6cfcff' User entered 'No (N)'	System	25 Aug 2020 18:50:23
	System	25 Aug 2020 18:50:23



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:49:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ba1e251f-247a-4ae8-8051-ee6e7d6cfcff' User entered 'None (1)'	System	25 Aug 2020 18:50:23
	System	25 Aug 2020 18:50:23

**US3032263**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ba1e251f-247a-4ae8-8051-ee6e7d6cfcff' User entered '25 Aug 2020 13:50'	System	25 Aug 2020 18:50:23
	System	25 Aug 2020 18:50:23

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 7'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:12', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '813bed1b-9c92-4cae-8597-bc57a4334ed8'	System	27 Aug 2020 03:36:31
User entered 'None (1)'	System	27 Aug 2020 03:36:31

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '813bed1b-9c92-4cae-8597-bc57a4334ed8' User entered 'No (N)'	System	27 Aug 2020 03:36:31
	System	27 Aug 2020 03:36:31

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:22', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '813bed1b-9c92-4cae-8597-bc57a4334ed8' User entered 'No (N)'	System	27 Aug 2020 03:36:31
	System	27 Aug 2020 03:36:31



US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '813bed1b-9c92-4cae-8597-bc57a4334ed8' User entered 'None (1)'	System	27 Aug 2020 03:36:31
	System	27 Aug 2020 03:36:31

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:29', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '813bed1b-9c92-4cae-8597-bc57a4334ed8' User entered '26 Aug 2020 22:36'	System	27 Aug 2020 03:36:31
	System	27 Aug 2020 03:36:31

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'None (0)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:40:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269' User entered 'No (N)'	System	20 Aug 2020 17:41:09
	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T12:41:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '20f52f32-d7bc-4f7f-bc53-222d4c91a269'	System	20 Aug 2020 17:41:09
User entered '20 Aug 2020 12:41'	System	20 Aug 2020 17:41:09

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 12:25'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 14:55'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:09:58



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:39', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:43', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:52', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:57:58', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered 'None (0)'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:58:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4'	System	20 Aug 2020 20:58:11
User entered 'No (N)'	System	20 Aug 2020 20:58:11

**US3032263**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-20T15:58:09', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f703c9ef-22fd-4302-8bcd-d90e5ccbc2b4' User entered '20 Aug 2020 15:58'	System	20 Aug 2020 20:58:11
	System	20 Aug 2020 20:58:11



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '20 Aug 2020 15:50'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 2'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:45', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:56:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'None (0)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:57:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered 'No (N)'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-21T22:57:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b2c25048-cce0-4178-af35-5b69e9726236' User entered '21 Aug 2020 22:57'	System	22 Aug 2020 03:57:12
	System	22 Aug 2020 03:57:12

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 3'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:45', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:48', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:56', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'None (0)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:13:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered 'No (N)'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-22T12:14:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd7d97cbd-87ee-43f8-80b5-e55bcbb5dbec' User entered '22 Aug 2020 12:14'	System	22 Aug 2020 17:14:08
	System	22 Aug 2020 17:14:08

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:09:58



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 4'	System	20 Aug 2020 17:09:58

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:24:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered 'None (0)'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:13', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9'	System	23 Aug 2020 17:25:17
User entered 'No (N)'	System	23 Aug 2020 17:25:17



**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-23T12:25:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '5bb88750-ce25-4b41-9bdd-3bcb6b021aa9' User entered '23 Aug 2020 12:25'	System	23 Aug 2020 17:25:17
	System	23 Aug 2020 17:25:17

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 5'	System	20 Aug 2020 17:09:58

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:13', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:15', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered 'None (0)'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a'	System	24 Aug 2020 17:04:25
User entered 'No (N)'	System	24 Aug 2020 17:04:25

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-24T12:04:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'cdd9d82f-1389-476a-bf43-f845c20e9e6a' User entered '24 Aug 2020 12:04'	System	24 Aug 2020 17:04:25
	System	24 Aug 2020 17:04:25

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 6'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:12', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:22', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:24', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered 'None (0)'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:30', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789'	System	25 Aug 2020 18:50:38
User entered 'No (N)'	System	25 Aug 2020 18:50:38

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-25T13:50:34', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'babb9214-41e8-4539-aa9f-5a4d19389789' User entered '25 Aug 2020 13:50'	System	25 Aug 2020 18:50:38
	System	25 Aug 2020 18:50:38

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:09:58



**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 7'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:54', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'None (0)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04



US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:36:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered 'No (N)'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-08-26T22:37:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'deba20b3-7234-42de-a468-4e957c5531e2' User entered '26 Aug 2020 22:37'	System	27 Aug 2020 03:37:04
	System	27 Aug 2020 03:37:04

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:09:58

US3032263

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:35:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:36

**US3032263**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:35:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '27 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:36

US3032263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:35:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:36

US3032263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:35:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:36



US3032263

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:35:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:39

**US3032263**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'I'	System	22 Sep 2020 14:47:39

**US3032263**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:53

US3032263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '3 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:53

US3032263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:53

US3032263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:53

US3032263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
DataPoint Verified.		17 Dec 2020 19:37:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:47:56

US3032263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:04:25
User entered 'I'	System	22 Sep 2020 14:47:56



US3032263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
DataPoint Verified.		14 Apr 2021 20:55:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:06

US3032263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
DataPoint Verified.		14 Apr 2021 20:55:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	22 Sep 2020 14:48:21
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Sep 2020 14:48:21
User entered '10 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:21
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 14:48:06
User entered '22 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:06

US3032263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
DataPoint Verified.		14 Apr 2021 20:55:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:06

US3032263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
DataPoint Verified.		14 Apr 2021 20:55:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:06

US3032263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
DataPoint Verified.		14 Apr 2021 20:55:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:25

US3032263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:35
User entered 'I'	System	22 Sep 2020 14:48:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:34

US3032263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:34



US3032263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:34

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'VISIT2'	System	22 Sep 2020 14:48:34

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '08:48'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '22 Sep 2020 08:48'	System	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43



US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '51'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'bpm'	System	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'breaths/min'	System	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '120'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	22 Sep 2020 15:16:43



US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '60'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	22 Sep 2020 15:16:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '10:12'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '22 Sep 2020 10:12'	System	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25



US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '61'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'bpm'	System	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'breaths/min'	System	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '135'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	22 Sep 2020 15:17:25



US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '79'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	22 Sep 2020 15:17:25

US3032263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:38:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:43

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 14:48:56



US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '09:41'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '22 Sep 2020 09:41'	System	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:20
User entered 'ONCE'	System	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 14:48:56

US3032263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:11

US3032263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:11



US3032263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '09:08'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:11

US3032263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '22 Sep 2020 09:08'	System	22 Sep 2020 14:49:11

US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '22 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:39:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '09:00'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '22 Sep 2020 09:00'	System	22 Sep 2020 14:49:23

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23



US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:39:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

US3032263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:39:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Sep 2020 14:49:23

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered empty.	System	22 Sep 2020 14:49:23

US3032263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:39:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	22 Sep 2020 14:49:26
	(b) (4)	

**US3032263**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	22 Sep 2020 14:49:26

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:14', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a0e78184-bac2-49f8-8566-81d0d622a2d1' User entered 'Yes (Y)'	System	22 Sep 2020 15:12:34
	System	22 Sep 2020 15:12:34

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:22', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a0e78184-bac2-49f8-8566-81d0d622a2d1' User entered '97.7'	System	22 Sep 2020 15:12:34
	System	22 Sep 2020 15:12:34



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a0e78184-bac2-49f8-8566-81d0d622a2d1' User entered 'No (N)'	System	22 Sep 2020 15:12:34
	System	22 Sep 2020 15:12:34

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:31', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a0e78184-bac2-49f8-8566-81d0d622a2d1' User entered '22 Sep 2020 10:12'	System	22 Sep 2020 15:12:34
	System	22 Sep 2020 15:12:34

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 10:01'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 12:31'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:25:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9f53a83b-69b2-4cd7-914f-347a8bad9f7a' User entered 'Yes (Y)'	System	22 Sep 2020 19:26:18
	System	22 Sep 2020 19:26:18

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9f53a83b-69b2-4cd7-914f-347a8bad9f7a' User entered '97.8'	System	22 Sep 2020 19:26:18
	System	22 Sep 2020 19:26:18

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9f53a83b-69b2-4cd7-914f-347a8bad9f7a' User entered 'No (N)'	System	22 Sep 2020 19:26:18
	System	22 Sep 2020 19:26:18



**US3032263**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9f53a83b-69b2-4cd7-914f-347a8bad9f7a' User entered '22 Sep 2020 14:26'	System	22 Sep 2020 19:26:18
	System	22 Sep 2020 19:26:18

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 13:26'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 2'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:56:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f51e67f1-fcb9-4490-9ecb-d1e5c6459ecf' User entered 'Yes (Y)'	System	24 Sep 2020 12:57:05
	System	24 Sep 2020 12:57:05

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:56:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f51e67f1-fcb9-4490-9ecb-d1e5c6459ecf' User entered '97.6'	System	24 Sep 2020 12:57:05
	System	24 Sep 2020 12:57:05

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:56:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f51e67f1-fcb9-4490-9ecb-d1e5c6459ecf' User entered 'No (N)'	System	24 Sep 2020 12:57:05
	System	24 Sep 2020 12:57:05

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f51e67f1-fcb9-4490-9ecb-d1e5c6459ecf' User entered '24 Sep 2020 07:57'	System	24 Sep 2020 12:57:05
	System	24 Sep 2020 12:57:05



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 3'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:20', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '55bcdd28-cf27-4f39-b41d-b29ae8b36621' User entered 'Yes (Y)'	System	24 Sep 2020 17:34:38
	System	24 Sep 2020 17:34:38

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '55bcdd28-cf27-4f39-b41d-b29ae8b36621' User entered '97.7'	System	24 Sep 2020 17:34:38
	System	24 Sep 2020 17:34:38

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '55bcdd28-cf27-4f39-b41d-b29ae8b36621' User entered 'No (N)'	System	24 Sep 2020 17:34:38
	System	24 Sep 2020 17:34:38

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '55bcdd28-cf27-4f39-b41d-b29ae8b36621' User entered '24 Sep 2020 12:34'	System	24 Sep 2020 17:34:38
	System	24 Sep 2020 17:34:38

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:48:56



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 4'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:07:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd5450eff-eb73-48a3-ae49-c326bf18449b' User entered 'Yes (Y)'	System	25 Sep 2020 17:08:13
	System	25 Sep 2020 17:08:13

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd5450eff-eb73-48a3-ae49-c326bf18449b' User entered '97.6'	System	25 Sep 2020 17:08:13
	System	25 Sep 2020 17:08:13

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd5450eff-eb73-48a3-ae49-c326bf18449b' User entered 'No (N)'	System	25 Sep 2020 17:08:13
	System	25 Sep 2020 17:08:13

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'd5450eff-eb73-48a3-ae49-c326bf18449b' User entered '25 Sep 2020 12:08'	System	25 Sep 2020 17:08:13
	System	25 Sep 2020 17:08:13

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:48:56



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 5'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'df3b2e09-1d03-4ab0-8e5b-e3de1d234a0b' User entered 'Yes (Y)'	System	26 Sep 2020 18:00:29
	System	26 Sep 2020 18:00:29

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'df3b2e09-1d03-4ab0-8e5b-e3de1d234a0b' User entered '97.6'	System	26 Sep 2020 18:00:29
	System	26 Sep 2020 18:00:29

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:22', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'df3b2e09-1d03-4ab0-8e5b-e3de1d234a0b' User entered 'No (N)'	System	26 Sep 2020 18:00:29
	System	26 Sep 2020 18:00:29

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:25', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'df3b2e09-1d03-4ab0-8e5b-e3de1d234a0b' User entered '26 Sep 2020 13:00'	System	26 Sep 2020 18:00:29
	System	26 Sep 2020 18:00:29

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 6'	System	22 Sep 2020 14:48:56



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '0bdf1393-d2c7-4c1e-a8a7-65f8071a30ca' User entered 'Yes (Y)'	System	28 Sep 2020 00:45:20
	System	28 Sep 2020 00:45:20

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '0bdf1393-d2c7-4c1e-a8a7-65f8071a30ca' User entered '96.9'	System	28 Sep 2020 00:45:20
	System	28 Sep 2020 00:45:20

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '0bdf1393-d2c7-4c1e-a8a7-65f8071a30ca' User entered 'No (N)'	System	28 Sep 2020 00:45:20
	System	28 Sep 2020 00:45:20

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '0bdf1393-d2c7-4c1e-a8a7-65f8071a30ca'	System	28 Sep 2020 00:45:20
User entered '27 Sep 2020 19:45'	System	28 Sep 2020 00:45:20

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 7'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8cfcc761-db56-40a4-8e5b-dd46374de764' User entered 'Yes (Y)'	System	29 Sep 2020 13:11:49
	System	29 Sep 2020 13:11:49



US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:41', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8cfcc761-db56-40a4-8e5b-dd46374de764' User entered '97.6'	System	29 Sep 2020 13:11:49
	System	29 Sep 2020 13:11:49

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8cfcc761-db56-40a4-8e5b-dd46374de764'	System	29 Sep 2020 13:11:49
User entered 'No (N)'	System	29 Sep 2020 13:11:49

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8cfcc761-db56-40a4-8e5b-dd46374de764' User entered '29 Sep 2020 08:11'	System	29 Sep 2020 13:11:49
	System	29 Sep 2020 13:11:49

US3032263

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:43', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8763f97a-2363-471f-a5bc-0fb583a316c3'	System	22 Sep 2020 15:13:08
User entered 'None (1)'	System	22 Sep 2020 15:13:08

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8763f97a-2363-471f-a5bc-0fb583a316c3' User entered 'No (N)'	System	22 Sep 2020 15:13:08
	System	22 Sep 2020 15:13:08



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:54', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8763f97a-2363-471f-a5bc-0fb583a316c3' User entered 'No (N)'	System	22 Sep 2020 15:13:08
	System	22 Sep 2020 15:13:08

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:12:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8763f97a-2363-471f-a5bc-0fb583a316c3'	System	22 Sep 2020 15:13:08
User entered 'None (1)'	System	22 Sep 2020 15:13:08

**US3032263**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8763f97a-2363-471f-a5bc-0fb583a316c3'	System	22 Sep 2020 15:13:08
User entered '22 Sep 2020 10:13'	System	22 Sep 2020 15:13:08

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 10:01'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 12:31'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '94a42f6a-255e-4ef2-8b46-f0c95d946502'	System	22 Sep 2020 19:26:47
User entered 'None (1)'	System	22 Sep 2020 19:26:47

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '94a42f6a-255e-4ef2-8b46-f0c95d946502'	System	22 Sep 2020 19:26:47
User entered 'No (N)'	System	22 Sep 2020 19:26:47



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:39', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '94a42f6a-255e-4ef2-8b46-f0c95d946502'	System	22 Sep 2020 19:26:47
User entered 'No (N)'	System	22 Sep 2020 19:26:47

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '94a42f6a-255e-4ef2-8b46-f0c95d946502'	System	22 Sep 2020 19:26:47
User entered 'None (1)'	System	22 Sep 2020 19:26:47

**US3032263**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:45', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '94a42f6a-255e-4ef2-8b46-f0c95d946502'	System	22 Sep 2020 19:26:47
User entered '22 Sep 2020 14:26'	System	22 Sep 2020 19:26:47

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 13:26'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 2'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:04', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '88177e13-5c66-40fa-b994-73714b4c69cb' User entered 'None (1)'	System	24 Sep 2020 12:57:22
	System	24 Sep 2020 12:57:22

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '88177e13-5c66-40fa-b994-73714b4c69cb' User entered 'No (N)'	System	24 Sep 2020 12:57:22
	System	24 Sep 2020 12:57:22



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:13', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '88177e13-5c66-40fa-b994-73714b4c69cb' User entered 'No (N)'	System	24 Sep 2020 12:57:22
	System	24 Sep 2020 12:57:22

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '88177e13-5c66-40fa-b994-73714b4c69cb' User entered 'None (1)'	System	24 Sep 2020 12:57:22
	System	24 Sep 2020 12:57:22

**US3032263**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:20', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '88177e13-5c66-40fa-b994-73714b4c69cb' User entered '24 Sep 2020 07:57'	System	24 Sep 2020 12:57:22
	System	24 Sep 2020 12:57:22

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 3'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8ec75591-a093-43ab-9464-2c0fca645db2' User entered 'None (1)'	System	24 Sep 2020 17:34:55
	System	24 Sep 2020 17:34:55

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8ec75591-a093-43ab-9464-2c0fca645db2'	System	24 Sep 2020 17:34:55
User entered 'No (N)'	System	24 Sep 2020 17:34:55



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:46', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8ec75591-a093-43ab-9464-2c0fca645db2'	System	24 Sep 2020 17:34:55
User entered 'No (N)'	System	24 Sep 2020 17:34:55

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8ec75591-a093-43ab-9464-2c0fca645db2'	System	24 Sep 2020 17:34:55
User entered 'None (1)'	System	24 Sep 2020 17:34:55

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:52', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8ec75591-a093-43ab-9464-2c0fca645db2'	System	24 Sep 2020 17:34:55
User entered '24 Sep 2020 12:34'	System	24 Sep 2020 17:34:55

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 4'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:14', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'af2c6a3c-2ebf-45cc-b017-48c7c942ee19'	System	25 Sep 2020 17:09:36
User entered 'None (1)'	System	25 Sep 2020 17:09:36

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'af2c6a3c-2ebf-45cc-b017-48c7c942ee19'	System	25 Sep 2020 17:09:36
User entered 'No (N)'	System	25 Sep 2020 17:09:36



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'af2c6a3c-2ebf-45cc-b017-48c7c942ee19' User entered 'No (N)'	System	25 Sep 2020 17:09:36
	System	25 Sep 2020 17:09:36

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:22', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'af2c6a3c-2ebf-45cc-b017-48c7c942ee19'	System	25 Sep 2020 17:09:36
User entered 'None (1)'	System	25 Sep 2020 17:09:36

**US3032263**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'af2c6a3c-2ebf-45cc-b017-48c7c942ee19' User entered '25 Sep 2020 12:08'	System	25 Sep 2020 17:09:36
	System	25 Sep 2020 17:09:36

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 5'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:31', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '734789bc-f50f-467f-8522-d33e8ee7ad4a'	System	26 Sep 2020 18:00:49
User entered 'None (1)'	System	26 Sep 2020 18:00:49

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '734789bc-f50f-467f-8522-d33e8ee7ad4a' User entered 'No (N)'	System	26 Sep 2020 18:00:49
	System	26 Sep 2020 18:00:49



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '734789bc-f50f-467f-8522-d33e8ee7ad4a'	System	26 Sep 2020 18:00:49
User entered 'No (N)'	System	26 Sep 2020 18:00:49

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '734789bc-f50f-467f-8522-d33e8ee7ad4a' User entered 'None (1)'	System	26 Sep 2020 18:00:49
	System	26 Sep 2020 18:00:49

**US3032263**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:48', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '734789bc-f50f-467f-8522-d33e8ee7ad4a' User entered '26 Sep 2020 13:00'	System	26 Sep 2020 18:00:49
	System	26 Sep 2020 18:00:49

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 6'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:24', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '11582726-9251-402a-80c9-39b28f4c4f02'	System	28 Sep 2020 00:45:46
User entered 'None (1)'	System	28 Sep 2020 00:45:46

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '11582726-9251-402a-80c9-39b28f4c4f02'	System	28 Sep 2020 00:45:46
User entered 'No (N)'	System	28 Sep 2020 00:45:46



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:33', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '11582726-9251-402a-80c9-39b28f4c4f02'	System	28 Sep 2020 00:45:46
User entered 'No (N)'	System	28 Sep 2020 00:45:46

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:39', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '11582726-9251-402a-80c9-39b28f4c4f02'	System	28 Sep 2020 00:45:46
User entered 'None (1)'	System	28 Sep 2020 00:45:46

**US3032263**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '11582726-9251-402a-80c9-39b28f4c4f02' User entered '27 Sep 2020 19:45'	System	28 Sep 2020 00:45:46
	System	28 Sep 2020 00:45:46

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 7'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7f0324e8-b191-44ad-83a0-50e72b51d7d4'	System	29 Sep 2020 13:12:06
User entered 'None (1)'	System	29 Sep 2020 13:12:06

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:54', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7f0324e8-b191-44ad-83a0-50e72b51d7d4' User entered 'No (N)'	System	29 Sep 2020 13:12:06
	System	29 Sep 2020 13:12:06



US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:11:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7f0324e8-b191-44ad-83a0-50e72b51d7d4' User entered 'No (N)'	System	29 Sep 2020 13:12:06
	System	29 Sep 2020 13:12:06

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7f0324e8-b191-44ad-83a0-50e72b51d7d4' User entered 'None (1)'	System	29 Sep 2020 13:12:06
	System	29 Sep 2020 13:12:06

**US3032263**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:04', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '7f0324e8-b191-44ad-83a0-50e72b51d7d4' User entered '29 Sep 2020 08:12'	System	29 Sep 2020 13:12:06
	System	29 Sep 2020 13:12:06

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:13', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:21', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered 'None (0)'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143'	System	22 Sep 2020 15:13:34
User entered 'No (N)'	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T10:13:30', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '3dcc89e1-99cd-4a24-a34d-f171c47cd143' User entered '22 Sep 2020 10:13'	System	22 Sep 2020 15:13:34
	System	22 Sep 2020 15:13:34

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 10:01'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 12:31'	System	22 Sep 2020 14:48:56



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:50', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:26:58', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:27:02', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:27:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:27:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'None (0)'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:27:14', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered 'No (N)'	System	22 Sep 2020 19:27:20



**US3032263**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-22T14:27:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1c0d3fce-75cb-48ff-a516-cfac2d2a9a62'	System	22 Sep 2020 19:27:20
User entered '22 Sep 2020 14:27'	System	22 Sep 2020 19:27:20

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '22 Sep 2020 13:26'	System	22 Sep 2020 14:48:56

**US3032263**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 2'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:25', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:28', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:34', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:39', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'None (0)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered 'No (N)'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T07:57:50', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e449c535-0530-4b05-b97c-a3aca23eadd6' User entered '24 Sep 2020 07:57'	System	24 Sep 2020 12:57:52
	System	24 Sep 2020 12:57:52

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 3'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:34:58', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'None (0)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered 'No (N)'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-24T12:35:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06580357-5b55-4531-9808-acfe09ab1607' User entered '24 Sep 2020 12:35'	System	24 Sep 2020 17:35:21
	System	24 Sep 2020 17:35:21

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:48:56



**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 4'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:29', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:32', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:44', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:46', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:49', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'None (0)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered 'No (N)'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-25T12:08:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '86fda22d-8c85-4518-8773-5b9923ca262f' User entered '25 Sep 2020 12:08'	System	25 Sep 2020 17:09:48
	System	25 Sep 2020 17:09:48

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 5'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered 'None (0)'	System	26 Sep 2020 18:01:22

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:00:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered 'None (0)'	System	26 Sep 2020 18:01:22

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92' User entered 'None (0)'	System	26 Sep 2020 18:01:22
	System	26 Sep 2020 18:01:22



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92' User entered 'None (0)'	System	26 Sep 2020 18:01:22
	System	26 Sep 2020 18:01:22

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:09', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered 'None (0)'	System	26 Sep 2020 18:01:22

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:12', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered 'None (0)'	System	26 Sep 2020 18:01:22

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered 'No (N)'	System	26 Sep 2020 18:01:22

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-26T13:01:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b6d96eeb-bf34-41ed-a553-bdd9733f5f92'	System	26 Sep 2020 18:01:22
User entered '26 Sep 2020 13:01'	System	26 Sep 2020 18:01:22

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 6'	System	22 Sep 2020 14:48:56



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:54', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:45:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:46:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:46:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'None (0)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:46:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered 'No (N)'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-27T19:46:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2368c746-73f7-40ea-8ccb-58cbdf6ef7c9' User entered '27 Sep 2020 19:46'	System	28 Sep 2020 00:46:11
	System	28 Sep 2020 00:46:11



**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	22 Sep 2020 14:48:56
User entered 'Day 7'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:10', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:12', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:15', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28



US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'None (0)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered 'No (N)'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

**US3032263**

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

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

**Generated On: 09 Jun 2021 14:55:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-09-29T08:12:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c0f55e5a-4eed-4f4a-9b1c-767d115c184f' User entered '29 Sep 2020 08:12'	System	29 Sep 2020 13:12:28
	System	29 Sep 2020 13:12:28

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:48:56

US3032263

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:48:56

**US3032263**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:04:00
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Sep 2020 19:27:30
	(b) (4)	

US3032263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:04:00
User entered '29 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 19:27:30

US3032263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:04:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 19:27:30



US3032263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:04:00
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 19:27:30

US3032263

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:53
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:04:00
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 19:27:35

**US3032263**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	29 Sep 2020 19:27:35

**US3032263**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:23:57

**US3032263**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:23:57

**US3032263**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:23:57

US3032263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:23:57

US3032263

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:45:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:25:05



**US3032263**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	06 Oct 2020 16:25:05

US3032263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:54:41

**US3032263**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:54:41

US3032263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:54:41

US3032263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:00
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:54:41

US3032263

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:03

**US3032263**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	19 Oct 2020 22:55:03

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:53
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:27



US3032263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:53
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:27

US3032263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:42:53
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:27

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'VISIT3'	System	19 Oct 2020 22:55:27

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '17:24'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '19 Oct 2020 17:24'	System	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57



US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '49'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'bpm'	System	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'breaths/min'	System	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '115'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	19 Oct 2020 22:55:57



US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '63'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'mmHg'	System	19 Oct 2020 22:55:57

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45

US3032263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45

US3032263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:38
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:56:04

US3032263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:38
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:56:04

US3032263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:56:13

US3032263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:56:13



**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:43:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered '17:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:56:13

US3032263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered '19 Oct 2020 17:40'	System	19 Oct 2020 22:56:13

US3032263

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		17 Dec 2020 19:44:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 22:57:23

**US3032263**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	19 Oct 2020 22:57:23

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 64'	System	20 Aug 2020 17:09:58

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

[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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-20T05:57:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '09884278-6729-4837-9322-da8e4dd3a513'	System	20 Oct 2020 10:58:02
User entered 'No (N)'	System	20 Oct 2020 10:58:02

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

Have you been exposed to someone with 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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-20T05:57:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '09884278-6729-4837-9322-da8e4dd3a513'	System	20 Oct 2020 10:58:02
User entered 'No (N)'	System	20 Oct 2020 10:58:02

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-20T05:57:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '09884278-6729-4837-9322-da8e4dd3a513' User entered '20 Oct 2020 05:57:59'	System	20 Oct 2020 10:58:02
	System	20 Oct 2020 10:58:02



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:09:58

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 71'	System	20 Aug 2020 17:09:58

US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

[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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-27T07:53:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f302dad5-f2ff-42a0-a279-0c73b76fa56c'	System	27 Oct 2020 12:54:24
User entered 'No (N)'	System	27 Oct 2020 12:54:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-27T07:54:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f302dad5-f2ff-42a0-a279-0c73b76fa56c'	System	27 Oct 2020 12:54:24
User entered 'No (N)'	System	27 Oct 2020 12:54:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-10-27T07:54:18', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f302dad5-f2ff-42a0-a279-0c73b76fa56c' User entered '27 Oct 2020 07:54:18'	System	27 Oct 2020 12:54:24
	System	27 Oct 2020 12:54:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:09:58



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 78'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-03T06:20:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '35d2afa4-3e37-4928-ace4-36089ddcc313'	System	03 Nov 2020 12:20:14
User entered 'No (N)'	System	03 Nov 2020 12:20:14

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Have you been exposed to someone with 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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-03T06:20:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '35d2afa4-3e37-4928-ace4-36089ddcc313'	System	03 Nov 2020 12:20:14
User entered 'No (N)'	System	03 Nov 2020 12:20:14

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-03T06:20:12', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '35d2afa4-3e37-4928-ace4-36089ddcc313' User entered '03 Nov 2020 06:20:12'	System	03 Nov 2020 12:20:14
	System	03 Nov 2020 12:20:14

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered 'Day 92'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-17T21:16:21', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8fc03d93-dc28-461d-9783-e11da46f1908'	System	18 Nov 2020 03:17:41
User entered 'No (N)'	System	18 Nov 2020 03:17:41



US3032263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:16

Have you been exposed to someone with 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)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-17T21:16:31', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8fc03d93-dc28-461d-9783-e11da46f1908'	System	18 Nov 2020 03:17:41
User entered 'No (N)'	System	18 Nov 2020 03:17:41

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-17T21:17:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '8fc03d93-dc28-461d-9783-e11da46f1908' User entered '17 Nov 2020 21:17:38'	System	18 Nov 2020 03:17:41
	System	18 Nov 2020 03:17:41

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:15
Data entry locked.	System	20 Aug 2020 17:09:58
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:09:58

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-24T08:50:45', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6974f603-c7b4-454d-9f96-9551236355c9' User entered 'No (N)'	System	24 Nov 2020 14:51:16
	System	24 Nov 2020 14:51:16

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-24T08:50:56', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6974f603-c7b4-454d-9f96-9551236355c9' User entered 'No (N)'	System	24 Nov 2020 14:51:16
	System	24 Nov 2020 14:51:16

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-24T08:51:14', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '6974f603-c7b4-454d-9f96-9551236355c9' User entered '24 Nov 2020 08:51:14'	System	24 Nov 2020 14:51:16
	System	24 Nov 2020 14:51:16



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-28T08:06:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e81e6036-433e-46bd-b3bb-ab86d27c9f3f'	System	28 Nov 2020 14:06:24
User entered 'No (N)'	System	28 Nov 2020 14:06:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-28T08:06:19', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e81e6036-433e-46bd-b3bb-ab86d27c9f3f' User entered 'No (N)'	System	28 Nov 2020 14:06:24
	System	28 Nov 2020 14:06:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-11-28T08:06:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e81e6036-433e-46bd-b3bb-ab86d27c9f3f' User entered '28 Nov 2020 08:06:23'	System	28 Nov 2020 14:06:24
	System	28 Nov 2020 14:06:24

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:46:11

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:49:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered 'Yes (Y)'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:49:48', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'Yes (Y)'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Please 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:49:56', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'Yes (Y)'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '1'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '0'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Please 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:50:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'Yes (Y)'	System	05 Dec 2020 14:51:19



**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Please 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:51:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de'	System	05 Dec 2020 14:51:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-05T08:51:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '42ace67e-f6b0-4985-8c58-0ad2c2ea27de' User entered '05 Dec 2020 08:51:08'	System	05 Dec 2020 14:51:19
	System	05 Dec 2020 14:51:19

**US3032263**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-13T10:55:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '38d8e3ba-63f1-4937-a855-4bede73d7e5e' User entered 'Yes (Y)'	System	13 Dec 2020 16:55:48
	System	13 Dec 2020 16:55:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-13T10:55:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '38d8e3ba-63f1-4937-a855-4bede73d7e5e' User entered 'No (N)'	System	13 Dec 2020 16:55:48
	System	13 Dec 2020 16:55:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-13T10:55:30', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '38d8e3ba-63f1-4937-a855-4bede73d7e5e' User entered 'No (N)'	System	13 Dec 2020 16:55:48
	System	13 Dec 2020 16:55:48



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-13T10:55:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '38d8e3ba-63f1-4937-a855-4bede73d7e5e' User entered 'No (N)'	System	13 Dec 2020 16:55:48
	System	13 Dec 2020 16:55:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-13T10:55:45', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '38d8e3ba-63f1-4937-a855-4bede73d7e5e' User entered '13 Dec 2020 10:55:45'	System	13 Dec 2020 16:55:48
	System	13 Dec 2020 16:55:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-22T18:01:31', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ca0d6015-3584-45da-97fb-77166002fef2' User entered 'No (N)'	System	23 Dec 2020 00:01:45
	System	23 Dec 2020 00:01:45

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-22T18:01:38', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ca0d6015-3584-45da-97fb-77166002fef2'	System	23 Dec 2020 00:01:45
User entered 'No (N)'	System	23 Dec 2020 00:01:45

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-22T18:01:41', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ca0d6015-3584-45da-97fb-77166002fef2' User entered '22 Dec 2020 18:01:41'	System	23 Dec 2020 00:01:45
	System	23 Dec 2020 00:01:45



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-26T08:31:47', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b351f17f-180a-4f86-89aa-9beda93d13bf' User entered 'No (N)'	System	26 Dec 2020 14:31:57

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-26T08:31:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b351f17f-180a-4f86-89aa-9beda93d13bf' User entered 'No (N)'	System	26 Dec 2020 14:31:57

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2020-12-26T08:31:55', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'b351f17f-180a-4f86-89aa-9beda93d13bf' User entered '26 Dec 2020 08:31:55'	System	26 Dec 2020 14:31:57
	System	26 Dec 2020 14:31:57

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-06T10:22:17', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9d194646-9b27-4b15-847e-74cccf7655b1' User entered 'No (N)'	System	06 Jan 2021 16:22:33
	System	06 Jan 2021 16:22:33

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-06T10:22:23', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9d194646-9b27-4b15-847e-74cccf7655b1'	System	06 Jan 2021 16:22:33
User entered 'No (N)'	System	06 Jan 2021 16:22:33

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-06T10:22:26', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '9d194646-9b27-4b15-847e-74cccf7655b1' User entered '06 Jan 2021 10:22:26'	System	06 Jan 2021 16:22:33
	System	06 Jan 2021 16:22:33

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-11T12:00:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1e72a5d0-9ff8-4703-9640-a7258424b022'	System	11 Jan 2021 18:01:48
User entered 'Yes (Y)'	System	11 Jan 2021 18:01:48



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-11T12:00:59', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1e72a5d0-9ff8-4703-9640-a7258424b022'	System	11 Jan 2021 18:01:48
User entered 'No (N)'	System	11 Jan 2021 18:01:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-11T12:01:06', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1e72a5d0-9ff8-4703-9640-a7258424b022' User entered 'No (N)'	System	11 Jan 2021 18:01:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-11T12:01:15', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1e72a5d0-9ff8-4703-9640-a7258424b022' User entered 'No (N)'	System	11 Jan 2021 18:01:48
	System	11 Jan 2021 18:01:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-11T12:01:20', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '1e72a5d0-9ff8-4703-9640-a7258424b022' User entered '11 Jan 2021 12:01:20'	System	11 Jan 2021 18:01:48
	System	11 Jan 2021 18:01:48

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-16T09:14:53', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e0225b31-5ee8-4fe3-82c1-01312e93ec69' User entered 'No (N)'	System	16 Jan 2021 15:15:06
	System	16 Jan 2021 15:15:06



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-16T09:14:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e0225b31-5ee8-4fe3-82c1-01312e93ec69' User entered 'No (N)'	System	16 Jan 2021 15:15:06
	System	16 Jan 2021 15:15:06

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-16T09:15:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e0225b31-5ee8-4fe3-82c1-01312e93ec69' User entered '16 Jan 2021 09:15:01'	System	16 Jan 2021 15:15:06
	System	16 Jan 2021 15:15:06

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-25T12:06:57', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ace653ca-c400-4d42-9609-a9714be5feec'	System	25 Jan 2021 18:07:09
User entered 'No (N)'	System	25 Jan 2021 18:07:09

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-25T12:07:01', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ace653ca-c400-4d42-9609-a9714be5feec'	System	25 Jan 2021 18:07:09
User entered 'No (N)'	System	25 Jan 2021 18:07:09

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-25T12:07:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'ace653ca-c400-4d42-9609-a9714be5feec' User entered '25 Jan 2021 12:07:05'	System	25 Jan 2021 18:07:09
	System	25 Jan 2021 18:07:09



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-30T00:01:35', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '4d368fe7-0b71-49e5-b43f-2a2d8e5b7c15'	System	30 Jan 2021 06:02:17
User entered 'No (N)'	System	30 Jan 2021 06:02:17

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-30T00:01:40', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '4d368fe7-0b71-49e5-b43f-2a2d8e5b7c15'	System	30 Jan 2021 06:02:17
User entered 'No (N)'	System	30 Jan 2021 06:02:17

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-01-30T00:01:42', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '4d368fe7-0b71-49e5-b43f-2a2d8e5b7c15' User entered '30 Jan 2021 00:01:42'	System	30 Jan 2021 06:02:17
	System	30 Jan 2021 06:02:17

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-06T09:31:05', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'abb32e1f-5cf0-4d76-8faf-06c841c316d0' User entered 'No (N)'	System	06 Feb 2021 15:31:23
	System	06 Feb 2021 15:31:23

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-06T09:31:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'abb32e1f-5cf0-4d76-8faf-06c841c316d0' User entered 'No (N)'	System	06 Feb 2021 15:31:23

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-06T09:31:16', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'abb32e1f-5cf0-4d76-8faf-06c841c316d0'	System	06 Feb 2021 15:31:23
User entered '06 Feb 2021 09:31:16'	System	06 Feb 2021 15:31:23

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-13T00:50:07', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '054b4f41-acf0-4b19-b34f-6d09889e3c13' User entered 'No (N)'	System	13 Feb 2021 06:50:18
	System	13 Feb 2021 06:50:18



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-13T00:50:11', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '054b4f41-acf0-4b19-b34f-6d09889e3c13'	System	13 Feb 2021 06:50:18
User entered 'No (N)'	System	13 Feb 2021 06:50:18

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-13T00:50:15', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '054b4f41-acf0-4b19-b34f-6d09889e3c13' User entered '13 Feb 2021 00:50:15'	System	13 Feb 2021 06:50:18
	System	13 Feb 2021 06:50:18

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-20T20:38:51', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '508481a4-13b3-4412-839a-055914e07872'	System	21 Feb 2021 02:39:12
User entered 'No (N)'	System	21 Feb 2021 02:39:12

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-20T20:39:03', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '508481a4-13b3-4412-839a-055914e07872' User entered 'No (N)'	System	21 Feb 2021 02:39:12

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-20T20:39:08', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '508481a4-13b3-4412-839a-055914e07872'	System	21 Feb 2021 02:39:12
User entered '20 Feb 2021 20:39:08'	System	21 Feb 2021 02:39:12



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-27T08:32:44-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f5401151-29ef-4f6d-999c-5f368b5c158b' User entered 'No (N)'	System	27 Feb 2021 14:32:58
	System	27 Feb 2021 14:32:58

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-27T08:32:51-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f5401151-29ef-4f6d-999c-5f368b5c158b'	System	27 Feb 2021 14:32:58
User entered 'No (N)'	System	27 Feb 2021 14:32:58

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-27T08:32:54-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'f5401151-29ef-4f6d-999c-5f368b5c158b'	System	27 Feb 2021 14:32:58
User entered '27 Feb 2021 14:32:54'	System	27 Feb 2021 14:32:58

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-06T00:05:09-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '421fef89-be91-43b1-b5e1-ba3208051d75'	System	06 Mar 2021 06:12:50
User entered 'No (N)'	System	06 Mar 2021 06:12:50

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-06T00:05:17-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '421fef89-be91-43b1-b5e1-ba3208051d75'	System	06 Mar 2021 06:12:50
User entered 'No (N)'	System	06 Mar 2021 06:12:50

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-06T00:05:26-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '421fef89-be91-43b1-b5e1-ba3208051d75'	System	06 Mar 2021 06:12:50
User entered '06 Mar 2021 00:05:26'	System	06 Mar 2021 06:12:50

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-17T11:18:08-10:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '43c1b537-7347-4287-8654-b1d681ee18ce'	System	17 Mar 2021 21:18:22
User entered 'No (N)'	System	17 Mar 2021 21:18:22



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-17T11:18:13-10:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '43c1b537-7347-4287-8654-b1d681ee18ce'	System	17 Mar 2021 21:18:22
User entered 'No (N)'	System	17 Mar 2021 21:18:22

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-17T11:18:17-10:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '43c1b537-7347-4287-8654-b1d681ee18ce' User entered '17 Mar 2021 11:18:17'	System	17 Mar 2021 21:18:22
	System	17 Mar 2021 21:18:22

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-20T08:47:00-07:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '62d346f7-bac3-40f0-8863-e05c95ef6898'	System	20 Mar 2021 15:47:12
User entered 'No (N)'	System	20 Mar 2021 15:47:12

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-20T08:47:05-07:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '62d346f7-bac3-40f0-8863-e05c95ef6898'	System	20 Mar 2021 15:47:12
User entered 'No (N)'	System	20 Mar 2021 15:47:12

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-20T08:47:08-07:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '62d346f7-bac3-40f0-8863-e05c95ef6898'	System	20 Mar 2021 15:47:12
User entered '20 Mar 2021 08:47:08'	System	20 Mar 2021 15:47:12



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-27T08:07:54-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a53ed703-c0a9-4672-9e1d-0f98755a82e6'	System	27 Mar 2021 13:08:07
User entered 'No (N)'	System	27 Mar 2021 13:08:07

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-27T08:07:56-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a53ed703-c0a9-4672-9e1d-0f98755a82e6'	System	27 Mar 2021 13:08:07
User entered 'No (N)'	System	27 Mar 2021 13:08:07

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-03-27T08:08:04-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'a53ed703-c0a9-4672-9e1d-0f98755a82e6' User entered '27 Mar 2021 08:08:04'	System	27 Mar 2021 13:08:07
	System	27 Mar 2021 13:08:07

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-03T08:39:36-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c74b2029-ad34-459b-a5da-c34dadfb7e8c'	System	03 Apr 2021 13:39:46
User entered 'No (N)'	System	03 Apr 2021 13:39:46

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-03T08:39:39-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c74b2029-ad34-459b-a5da-c34dadfb7e8c'	System	03 Apr 2021 13:39:46
User entered 'No (N)'	System	03 Apr 2021 13:39:46

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-03T08:39:43-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'c74b2029-ad34-459b-a5da-c34dadfb7e8c' User entered '03 Apr 2021 08:39:43'	System	03 Apr 2021 13:39:46
	System	03 Apr 2021 13:39:46

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-10T06:56:02-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '80d05289-85fd-484a-9ae2-0ed166418d0e' User entered 'No (N)'	System	10 Apr 2021 11:56:16
	System	10 Apr 2021 11:56:16



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-10T06:56:08-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '80d05289-85fd-484a-9ae2-0ed166418d0e'	System	10 Apr 2021 11:56:16
User entered 'No (N)'	System	10 Apr 2021 11:56:16

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-10T06:56:11-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '80d05289-85fd-484a-9ae2-0ed166418d0e' User entered '10 Apr 2021 06:56:11'	System	10 Apr 2021 11:56:16
	System	10 Apr 2021 11:56:16

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-17T12:26:09-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06308e2c-fd21-4ab1-a8cc-59b559ebc008'	System	17 Apr 2021 17:26:20
User entered 'No (N)'	System	17 Apr 2021 17:26:20

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-17T12:26:14-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06308e2c-fd21-4ab1-a8cc-59b559ebc008'	System	17 Apr 2021 17:26:20
User entered 'No (N)'	System	17 Apr 2021 17:26:20

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-17T12:26:17-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '06308e2c-fd21-4ab1-a8cc-59b559ebc008'	System	17 Apr 2021 17:26:20
User entered '17 Apr 2021 12:26:17'	System	17 Apr 2021 17:26:20



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-26T12:19:30-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e5b66272-d8db-427c-9b11-a555fb628c35'	System	26 Apr 2021 17:19:41
User entered 'No (N)'	System	26 Apr 2021 17:19:41

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Have you been exposed to someone with 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 (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-26T12:19:34-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e5b66272-d8db-427c-9b11-a555fb628c35'	System	26 Apr 2021 17:19:41
User entered 'No (N)'	System	26 Apr 2021 17:19:41

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-04-26T12:19:39-05:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: 'e5b66272-d8db-427c-9b11-a555fb628c35'	System	26 Apr 2021 17:19:41
User entered '26 Apr 2021 12:19:39'	System	26 Apr 2021 17:19:41

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:46:11



**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:46:11

**US3032263**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:11
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:46:11

US3032263

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:55:16

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 12:22:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-27T08:33:04-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2fc3c5f3-46dc-4f40-ad3a-0207fe1f8cc9'	System	27 Feb 2021 14:33:13
User entered 'No (N)'	System	27 Feb 2021 14:33:13

**US3032263**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:22:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F79097-C3DB-4D58-BDBC-A94D392B7079)', Time: '2021-02-27T08:33:10-06:00', User OID: 'PatientReportedOutcome (US3032263)', ODM File OID: '2fc3c5f3-46dc-4f40-ad3a-0207fe1f8cc9'	System	27 Feb 2021 14:33:13
User entered '27 Feb 2021 14:33:10'	System	27 Feb 2021 14:33:13

US3032263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		14 Apr 2021 20:57:14
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:32

US3032263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		14 Apr 2021 20:57:14
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '18 Nov 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:32

US3032263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		14 Apr 2021 20:57:14
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:32

US3032263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		14 Apr 2021 20:57:14
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:32



US3032263

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
DataPoint Verified.		14 Apr 2021 20:57:07
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:36

**US3032263**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:45
User entered 'I'	System	26 Feb 2021 14:21:36

**US3032263**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:57:24
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:49

US3032263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:57:24
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '18 Dec 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:49

US3032263

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:57:24
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:49

**US3032263**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:57:24
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:49

US3032263

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:16:18
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:21:52

**US3032263**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
User entered 'I'	System	26 Feb 2021 14:21:52



**US3032263**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:59:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	26 Feb 2021 14:22:06
	(b) (4)	

US3032263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:59:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '18 Jan 2021'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:22:06

US3032263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:59:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:22:06

US3032263

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:59:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:22:06

US3032263

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 20:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:22:20

**US3032263**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
User entered 'I'	System	26 Feb 2021 14:22:20

**US3032263**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:00:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:24:49

US3032263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:00:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '16 Feb 2021'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:24:49



US3032263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:00:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:24:49

US3032263

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:00:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:24:49

US3032263

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
DataPoint Verified.		14 Apr 2021 21:00:13
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	26 Feb 2021 14:24:56

**US3032263**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:02
User entered 'I'	System	26 Feb 2021 14:24:56

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:25
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:46

US3032263

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:25
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:46

US3032263

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:25
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:46

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 21:48:46



US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54
	(b) (4)	

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54
	(b) (4)	

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54
	(b) (4)	

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54
	(b) (4)	

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54



**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:54

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:54

US3032263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:56
	(b) (4)	



US3032263

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:01:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:56
	(b) (4)	

US3032263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:02:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:58

US3032263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:02:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:58
	(b) (4)	

US3032263

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:02:04
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:58
	(b) (4)	

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 21:48:58

US3032263

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:02:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:49:01
	(b) (4)	

**US3032263**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 21:49:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 19:57:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:13



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 19:57:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '15:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:13

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered '4 Dec 2020 15:40'	System	07 Dec 2020 21:28:13

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 19:57:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:13

**US3032263**

**Folder: Covid-19 Assessment 04 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:55:16**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 19:57:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:13

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
Signature has been broken.	(b) (4)	22 Feb 2021 22:06:19
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	22 Feb 2021 22:06:19
User signature succeeded.	(b) (4)	08 Dec 2020 19:48:30
User entered 'Day 4 (Day 4)'	Kelsey Kelley (b) (4)	07 Dec 2020 21:28:55
	(b) (4)	

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered '%'	System	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:55

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Day 2 (Day 2)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '5 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:12



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Day 3 (Day 3)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '6 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:29:34

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '100'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered '%'	System	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '36.0' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:00:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:31

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '8 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:07:53

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 6 (Day 6)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '9 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '1' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	22 Feb 2021 22:08:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:08:01



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 7 (Day 7)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '10 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:09:50

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 8 (Day 8)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 22:10:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 22:10:29
User entered '11 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:29
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 22:10:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 9 (Day 9)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '12 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:37

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 10 (Day 10)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '13 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:10:48



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 11 (Day 11)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '14 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:11:23

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 12 (Day 12)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '15 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:43

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Kelsey Kelley (b) (4)	22 Feb 2021 22:13:04
User entered 'Day 15 (Day 15)'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Feb 2021 22:12:56
	(b) (4)	

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '16 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:12:56

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Day 14 (Day 14)'	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered '17 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered empty.	System	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:55:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:00:03
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:14



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User closed query 'As a test result was generated in preclarus please change the answer to Yes.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 04:00:21
DataPoint Verified.		02 Apr 2021 04:00:14
Query 'As a test result was generated in preclarus please change the answer to Yes.' answered with 'agreed after looking in preclarus this is "yes"' (Site from CRA).	Samantha Wieseler (b) (4)	24 Mar 2021 22:02:25
Signature has been broken.	Samantha Wieseler (b) (4)	24 Mar 2021 22:01:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	24 Mar 2021 22:01:45
User opened query 'As a test result was generated in preclarus please change the answer to Yes.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:02:46
DataPoint Un-verified.		24 Mar 2021 20:59:37
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 03:05:59
User closed query 'Per ETRTR: According to lab report dated 07Dec20 with accession number "1F608WM" COVID was detected. Please review and reconcile.' (Site from CRA).		24 Mar 2021 20:53:36
User closed query 'Per ETRTR: According to lab report dated 07Dec20 with accession number "1F608WM" COVID was detected. Please review and reconcile.' (Site from CRA).		24 Mar 2021 20:53:34
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 'updated' (Site from System).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:56:16
Query 'Per ETRTR: According to lab report dated 07Dec20 with accession number "1F608WM" COVID was detected. Please review and reconcile.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:54:12
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). DataPoint Un-verified.	System	23 Mar 2021 15:53:48
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:53:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:53:48
User opened query 'Per ETRTR: According to lab report dated 07Dec20 with accession number "1F608WM" COVID was detected. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 17:11:42
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[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)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:16

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User entered '1'	System	23 Mar 2021 15:53:48
User entered '0'	System	07 Dec 2020 21:30:51

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 04:00:39
DataPoint Un-verified.		24 Mar 2021 20:58:33
DataPoint Verified.		24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:59:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 15:59:25
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:59:25
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:58:57
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

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)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:59:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 15:59:25
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:59:25
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:58:57
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:59:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 15:59:25
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:59:25
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:58:57
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:59:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 15:59:25
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:59:25
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 15:58:57
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57



US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:55:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:42
User entered empty.	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 15:58:57

US3032263

Folder: Covid-19 Assessment 04 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:55:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:26:43
DataPoint Verified.		26 Feb 2021 20:02:53
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:28:21

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11



**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4)	07 Jan 2021 16:35:11
	(b) (4)	

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4)	07 Jan 2021 16:35:11
	(b) (4)	

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	07 Jan 2021 16:35:11
	(b) (4)	

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4)	07 Jan 2021 16:35:11
	(b) (4)	



**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11



**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
User closed query 'Per GCL LAB reconciliation Requery: Saliva: Per response, Saliva sample collected on the Convalescence visit Day 28 will be recorded on the DAY 28 log line of Saliva Collection form. Please review and update the Day 28 sample dated 07JAN2021 (Accession # 1F657459364) in EDC.' (Site from DM).		30 Mar 2021 06:42:16
Query 'Per GCL LAB reconciliation Requery: Saliva: Linden DeBoer Per response, Saliva sample collected on the Convalescence visit Day 28 will be recorded on the DAY 28 log line of Saliva Collection form. Please review and update the Day 28 sample dated 07JAN2021 (Accession # 1F657459364) in EDC.' answered with 'recoded under convalescent day 28 in edc' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Mar 2021 16:00:51
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:17:25
User opened query 'Per GCL LAB reconciliation Requery: Saliva: Per response, Saliva sample collected on the Convalescence visit Day 28 will be recorded on the DAY 28 log line of Saliva Collection form. Please review and update the Day 28 sample dated 07JAN2021 (Accession # 1F657459364) in EDC.' (Site from DM).		23 Feb 2021 06:53:26
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F657459364 is reported with 07JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:53:26
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F657459364 is reported with 07JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' answered with 'Day 28 sample was collected at Convalescent visit' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:00:03

US3032263

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F657459364 is reported with 07JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus 'Thank you' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Keith Vrbicky (b) (4) (b) (4)	09 Feb 2021 06:11:58  07 Jan 2021 19:17:55
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:30
DataPoint Verified.		26 Feb 2021 20:17:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:11

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:32
DataPoint Verified.		10 Mar 2021 23:21:10
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:24:08

US3032263

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:32
DataPoint Verified.		10 Mar 2021 23:21:10
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:24:08

US3032263

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:32
DataPoint Verified.		10 Mar 2021 23:21:10
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:24:08

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:32
User entered 'SICKD1'	System	07 Dec 2020 21:24:08



US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '11:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User entered '7 Dec 2020 11:40'	System	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '165.1' cm	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:25:57
DataPoint set to visible.	(b) (4) System	07 Dec 2020 21:24:08

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '56' kg	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:25:57
DataPoint set to visible.	(b) (4) System	07 Dec 2020 21:24:08

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '36.0' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57



US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User closed query 'Per the source the subjects heart rate was 44 BPM please update to reflect the source' (Site from CRA).		24 Mar 2021 20:43:28
DataPoint Verified.		24 Mar 2021 20:43:26
Query 'Per the source the subjects heart rate was 44 BPM please update to reflect the source' answered with 'pulse was retaken and recorded' (Site from CRA).		23 Mar 2021 16:01:30
DataPoint Un-verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:07:25
User opened query 'Per the source the subjects heart rate was 44 BPM please update to reflect the source' (Site from CRA).		26 Feb 2021 20:07:21
User signature succeeded.		26 Feb 2021 20:06:46
User entered '60' reason for change: Data Entry Error		
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	(b) (4)	
User entered '49' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	07 Dec 2020 21:26:37
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
User entered '44'	System	07 Dec 2020 21:26:05
	System	07 Dec 2020 21:26:05
	Kelsey Kelley (b) (4)	07 Dec 2020 21:26:05
	(b) (4)	
	System	07 Dec 2020 21:25:57
	Kelsey Kelley (b) (4)	07 Dec 2020 21:25:57
	(b) (4)	

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User entered 'bpm'	System	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '18'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User entered 'breaths/min'	System	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User entered 'mmHg'	System	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
DataPoint Verified.		26 Feb 2021 20:07:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '60'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:25:57



US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36
User entered 'mmHg'	System	07 Dec 2020 21:25:57

US3032263

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36

**US3032263**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:36

US3032263

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:41
DataPoint Verified.		26 Feb 2021 20:07:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:26:44

US3032263

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:41
DataPoint Verified.		26 Feb 2021 20:07:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:26:44

US3032263

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:16

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
DataPoint Verified.		26 Feb 2021 20:07:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:26:54

US3032263

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
DataPoint Verified.		26 Feb 2021 20:07:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:26:54

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:53
DataPoint Verified.		26 Feb 2021 20:07:43
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:33:49



US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:53
DataPoint Verified.		26 Feb 2021 20:07:43
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered '7 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:33:49

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:53
DataPoint Verified.		26 Feb 2021 20:07:43
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:33:49

**US3032263**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:53
User entered 'SICKD28'	System	07 Jan 2021 16:33:49

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '7 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '09:20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

**US3032263**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
User entered '7 Jan 2021 09:20'	System	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '165.1' cm	(b) (4) Kelsey Kelley (b) (4)	07 Jan 2021 22:43:48
DataPoint set to visible.	(b) (4) System	07 Jan 2021 16:33:49



US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '50' kg	(b) (4) Kelsey Kelley (b) (4)	07 Jan 2021 22:43:48
DataPoint set to visible.	(b) (4) System	07 Jan 2021 16:33:49

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '52'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

**US3032263**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
User entered 'bpm'	System	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
User entered 'breaths/min'	System	07 Jan 2021 22:43:48



US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
User entered 'mmHg'	System	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
DataPoint Verified.		26 Feb 2021 20:16:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:30:45
User entered '60'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 22:43:48

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58
User entered 'mmHg'	System	07 Jan 2021 22:43:48

**US3032263**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58

**US3032263**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:58

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:01
DataPoint Verified.		26 Feb 2021 20:16:49
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:31

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:01
DataPoint Verified.		26 Feb 2021 20:16:49
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered '7 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:31



US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:16

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:05
DataPoint Verified.		26 Feb 2021 20:17:13
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:42

US3032263

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:05
DataPoint Verified.		26 Feb 2021 20:17:13
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 07 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.		11 Feb 2021 08:57:17
' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 07 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	Samantha Wieseler (b) (4) (b) (4)	01 Feb 2021 22:41:28
' answered with 'will update accordingly' (Site from DM). User opened query 'Per Lab Recon: SARS-COV2: Sample dated 07 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4), (b) (6) (b) (4)	29 Jan 2021 08:04:14
' (Site from DM). User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:17:55
User entered '7 Jan 2021'	Kelsey Kelley (b) (4) (b) (4)	07 Jan 2021 16:35:42

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2233 of 3127

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:44
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:15

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:44
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:15

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:44
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:15

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 15:52:15

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:16**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:27:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:17:03



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
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	03 Feb 2021 15:52:55
User entered 'Yes (Y)' reason for change: Data Entry Error	System	03 Feb 2021 15:52:55
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	03 Feb 2021 15:52:55
User entered empty.	(b) (4)	
	System	03 Feb 2021 15:52:51
	Kelsey Kelley (b) (4)	03 Feb 2021 15:52:51
	(b) (4)	

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:16**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:27:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:17:03

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:16**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:16**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:52:51

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '1'	System	03 Feb 2021 15:52:51



**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'I'	System	03 Feb 2021 15:52:55
User entered empty.	System	03 Feb 2021 15:52:51

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered empty.	System	03 Feb 2021 15:56:38
DataPoint set to visible.	System	03 Feb 2021 15:52:55

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered empty.	System	03 Feb 2021 15:56:38
DataPoint set to visible.	System	03 Feb 2021 15:52:55

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '09:50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Feb 2021 09:50'	System	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'bpm'	System	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'breaths/min'	System	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '139'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:56:38

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered empty.	System	03 Feb 2021 15:56:38
DataPoint set to visible.	System	03 Feb 2021 15:52:55

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '11:12'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Feb 2021 11:12'	System	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '67'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'bpm'	System	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'breaths/min'	System	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	03 Feb 2021 15:57:41



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:11
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	03 Feb 2021 15:57:41

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:05

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:27:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:05

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mRNA-1273'	System	03 Feb 2021 15:54:44
DataPoint set to visible.	System	03 Feb 2021 15:52:55



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '10:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Feb 2021 10:40'	System	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:15
User entered 'ONCE'	System	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 15:54:44

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:17

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:17



US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '09:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:17

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Feb 2021 09:25'	System	03 Feb 2021 15:53:17

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:51
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:29

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:51
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '2 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:29

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:51
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '09:29'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:29

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:55:16**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Feb 2021 09:29'	System	03 Feb 2021 15:53:29

US3032263

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:29:56
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 Feb 2021 15:53:38

**US3032263**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'I'	System	03 Feb 2021 15:53:38



**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
DataPoint Verified.		10 Mar 2021 23:33:17
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Feb 2021 17:28:41

**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
DataPoint Verified.		10 Mar 2021 23:33:17
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '9 Feb 2021'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Feb 2021 17:28:41

**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
DataPoint Verified.		10 Mar 2021 23:33:17
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Feb 2021 17:28:41

**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
DataPoint Verified.		10 Mar 2021 23:33:17
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Feb 2021 17:28:41

US3032263

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
DataPoint Verified.		10 Mar 2021 23:33:21
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Feb 2021 17:28:48

**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User entered 'I'	System	24 Feb 2021 17:28:48

**US3032263**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:18
User entered '1'	System	24 Feb 2021 17:28:48
DataPoint set to visible.	System	24 Feb 2021 17:28:48

**US3032263**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:34:12
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:27:42



**US3032263**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:34:12
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:27:42

**US3032263**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:34:12
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:27:42

**US3032263**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'OLD29'	System	02 Mar 2021 17:27:42

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '09:05'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Mar 2021 09:05'	System	02 Mar 2021 17:30:05



**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'bpm'	System	02 Mar 2021 17:30:05

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'breaths/min'	System	02 Mar 2021 17:30:05

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '108'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05



US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	02 Mar 2021 17:30:05

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '70'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:30:05

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	02 Mar 2021 17:30:05

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '10:05'	(b) (4)	
	Kelsey Kelley (b) (4)	02 Mar 2021 17:31:54
	(b) (4)	

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Mar 2021 10:05'	System	02 Mar 2021 17:31:54



**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'bpm'	System	02 Mar 2021 17:31:54

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'breaths/min'	System	02 Mar 2021 17:31:54

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '120'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54



**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	02 Mar 2021 17:31:54

**US3032263**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:36:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '87'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:54

US3032263

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mmHg'	System	02 Mar 2021 17:31:54

US3032263

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:29:35

**US3032263**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:55:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:01
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:29:35

US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04

US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04

US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04



US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'mRNA-1273'	System	02 Mar 2021 17:31:04
DataPoint set to visible.	System	24 Feb 2021 17:28:48

**US3032263**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '2 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04

**US3032263**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '09:28'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04

**US3032263**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered '2 Mar 2021 09:28'	System	02 Mar 2021 17:31:04

US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:04

**US3032263**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:55:16**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:35
User entered 'ONCE'	System	02 Mar 2021 17:31:04

US3032263

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 17:31:04

US3032263

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
DataPoint Verified.		10 Mar 2021 23:37:41
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Mar 2021 17:31:12



**US3032263**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:55:41
User entered 'I'	System	02 Mar 2021 17:31:12

**US3032263**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
DataPoint Verified.		10 Mar 2021 23:38:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:33
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Mar 2021 14:06:49

**US3032263**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
DataPoint Verified.		10 Mar 2021 23:38:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:33
User entered '09 Mar 2021'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Mar 2021 14:06:49

**US3032263**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
DataPoint Verified.		10 Mar 2021 23:38:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Mar 2021 14:06:49

US3032263

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
DataPoint Verified.		10 Mar 2021 23:38:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Mar 2021 14:06:49

US3032263

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
DataPoint Verified.		10 Mar 2021 23:38:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:38:33
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Mar 2021 14:06:52

**US3032263**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:40:59
User entered 'I'	System	10 Mar 2021 14:06:52

**US3032263**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:47
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:47:31



**US3032263**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:47
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:47:31

**US3032263**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:47
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:47:31

**US3032263**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:16**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 21:47:31

US3032263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '15:00'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 15:00'	System	01 Apr 2021 21:48:12

US3032263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12



**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:12

US3032263

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:16

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '79'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:48:12



**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:53
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '86'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:12

**US3032263**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:48:12

US3032263

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:16

**US3032263**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:55:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 21:48:16

US3032263

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:25

**US3032263**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '1 Apr 2021'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:25
	(b) (4)	

**US3032263**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
User entered '15:07'	(b) (4) Kelsey Kelley (b) (4)	01 Apr 2021 21:48:25

**US3032263**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 15:07'	System	01 Apr 2021 21:48:25



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:55:16**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:08
DataPoint Verified.		26 Feb 2021 20:22:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:30:58

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:05:40
User entered 'USA-US032-2021-mRNA-1273-P301000005'	System	04 Feb 2021 20:05:35
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 20:05:35

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User closed query 'PV Query: Please complete the COVID-19 symptom log from 08 Dec 2020 through 17 Dec 2020' (Site from Safety).		23 Feb 2021 17:38:50
User closed query 'PV Query: Please confirm date and results of COVID testing, as information provided shows negative results.' (Site from Safety).		23 Feb 2021 17:38:22
Query 'PV Query: Please complete the COVID-19 symptom log from 08 Dec 2020 through 17 Dec 2020' answered with 'Updated symptom log' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:13:33
Query 'PV Query: Please confirm date and results of COVID testing, as information provided shows negative results.' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	22 Feb 2021 21:19:10
User opened query 'PV Query: Please complete the COVID-19 symptom log from 08 Dec 2020 through 17 Dec 2020' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 21:48:18
Query 'Please complete the COVID-19 symptom log from 08 Dec 2020 through 17 Dec 2020.' canceled (Site from Safety).		19 Feb 2021 21:48:06
User opened query 'Please complete the COVID-19 symptom log from 08 Dec 2020 through 17 Dec 2020.' (Site from Safety).		12 Feb 2021 03:27:06
User opened query 'PV Query: Please confirm date and results of COVID testing, as information provided shows negative results.' (Site from Safety).		12 Feb 2021 03:26:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:41:54
User closed query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:22:25
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Jan 2021 20:02:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Jan 2021 20:02:47
Data point term sent to Coder	System	09 Jan 2021 20:02:08

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Kelsey Kelley (b) (4)	09 Jan 2021 20:01:37
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Jan 2021 20:01:37
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	09 Jan 2021 20:01:37
	(b) (4)	
Query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term	Samantha Wieseler (b) (4)	09 Jan 2021 15:42:58
	(b) (4)	
' answered with 'will updated when more information is available' (Site from DM).		
User opened query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term	(b) (4), (b) (6)	30 Dec 2020 12:53:26
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	(b) (4)	
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import	07 Dec 2020 21:39:00
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 21:37:24
User entered 'Suspected covid-19'	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 04:24:20
DataPoint Un-verified.	Linden DeBoer (b) (4)	23 Mar 2021 15:55:08
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	23 Mar 2021 15:55:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	23 Mar 2021 15:55:08
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	04 Feb 2021 19:49:21
Signature has been broken.	System	04 Feb 2021 19:49:21
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Feb 2021 19:49:21
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	04 Feb 2021 19:49:04
User signature succeeded.	System	04 Feb 2021 19:49:04
User entered 'Yes (Y)'	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
	(b) (4)	07 Dec 2020 21:37:23
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	04 Feb 2021 19:49:04
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Feb 2021 19:49:04
Signature has been broken.	Linden DeBoer (b) (4)	04 Feb 2021 19:49:04
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 19:49:04
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	System	04 Feb 2021 19:48:34
User entered empty.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
	(b) (4)	07 Dec 2020 21:37:23
	Kelsey Kelley (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	(b) (4)	03 Feb 2021 15:20:45
User entered 'Grade 4 (Grade 4)' reason for change:	Kelsey Kelley (b) (4)	03 Feb 2021 15:20:45
New Information	(b) (4)	03 Feb 2021 15:20:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	07 Dec 2020 21:37:23
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	04 Feb 2021 19:48:34
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Feb 2021 15:21:04
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	03 Feb 2021 15:21:04
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	03 Feb 2021 15:21:04
Signature has been broken.	Kelsey Kelley (b) (4)	03 Feb 2021 15:21:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	03 Feb 2021 15:21:04
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Feb 2021 15:20:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4)	
	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered '7 Dec 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered '12 Dec 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:32:57
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:27:23
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 19:59:39
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 19:59:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 19:59:39
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:32:58
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:27:23
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	16 Apr 2021 19:59:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	16 Apr 2021 19:59:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered '5' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	



US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Linden DeBoer (b) (4)	04 Feb 2021 19:48:34
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:22:45
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)	23 Feb 2021 17:39:02
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 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	22 Feb 2021 21:19:27
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	22 Feb 2021 21:19:01
User entered 'SUBJECT WAS SEEN FOR COVID SYMPTOMS ON 07DEC2020. SUBJECTS HEART RATE WAS IRREGULAR AND SLOW. SUBJECT WAS DIZZY AND LIGHT HEADED. WE REFERRED SUBJECT TO THE NEAREST EMERGENCY DEPARTMENT. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR COVID-19. SUBJECT WAS NOTED TO HAVE INTERMITTENT MOBITZ II HEART BLOCK. update 22Feb: pt had a positive covid test collected on 04dec2020 and was notified of positive results 09dec2020. She also had a rapid covid pcr test performed at the ER on 07Dec2020 which was positive.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	22 Feb 2021 21:19:01

US3032263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:55:16

[Narrative](#)

Audit	User	Time (GMT)
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)	19 Feb 2021 21:48:55
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 18:21:08
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 20:33:16
	(b) (4)	
User entered 'subject was seen for COVID symptoms on 07Dec2020. subjects heart rate was irregular and slow. Subject was dizzy and light headed. We referred subject to the nearest emergency department. Subject was admitted to the hospital for COVID-19. Subject was noted to have intermittent Mobitz II heart block.' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Feb 2021 20:33:16
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'finishing up with medical records review. will update more once completed ' (Site from System).	(b) (4)	
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 15:21:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	07 Dec 2020 21:37:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:21:04
User entered '0'	System	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 21:37:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 19:59:39
User entered '1'	System	04 Feb 2021 19:48:34

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:43:25
User entered 'USA-US032-2021-mRNA-1273-P301000005'		05 Feb 2021 13:43:16



US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User		Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block second degree, LLT: Mobitz (type) II atrioventricular block - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	19 Mar 2021 14:02:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	19 Mar 2021 14:02:34
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block second degree, LLT: Type II second degree atrioventricular block - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	10 Mar 2021 11:55:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	10 Mar 2021 11:55:51
DataPoint Verified.	(b) (4), (b) (6)		26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	05 Feb 2021 19:41:54
Data point term sent to Coder	System		04 Feb 2021 20:22:15
User entered 'second degree Mobitz II AV Block, intermittent'	Linden DeBoer (b) (4)	(b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'No (N)'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	04 Feb 2021 20:21:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '7 Dec 2020'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'No (N)'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56



US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:22:45
User entered '08 Jan 2021' reason for change: New Information	Kelsey Kelley (b) (4)	22 Feb 2021 22:01:24
User closed query 'Please clarify end date (08 Jan 2021) of event as subject was discharged from hospital on 12 Dec 2020. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:45:16
Query 'Please clarify end date (08 Jan 2021) of event as subject was discharged from hospital on 12 Dec 2020. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'update' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:15
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:08
User entered '12 Jan 2021' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:08
User opened query 'Please clarify end date (08 Jan 2021) of event as subject was discharged from hospital on 12 Dec 2020. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 03:27:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:41:54
User entered '8 Jan 2021'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'I'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56



US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '7 Dec 2020'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '12 Dec 2020'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:22:45
User closed query ' Please confirm the number of days the subject was in ICU. Reported as 5 days for COVID-19 and 1 day for second degree Mobitz II AV block, intermittent.' (Site from Safety).		16 Feb 2021 16:45:20
Query ' Please confirm the number of days the subject was in ICU. Reported as 5 days for COVID-19 and 1 day for second degree Mobitz II AV block, intermittent.' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:20
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:08
User entered '5' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	12 Feb 2021 14:04:08
User opened query ' Please confirm the number of days the subject was in ICU. Reported as 5 days for COVID-19 and 1 day for second degree Mobitz II AV block, intermittent.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 03:28:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:41:54
User entered '1'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:21:56

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
Query 'Please confirm causality for Second degree Mobitz II AV block, intermittent as not related to study drug or procedure (causality email was not completed for this event). ' canceled (Site from Safety).		19 Feb 2021 21:47:00
User opened query 'Please confirm causality for Second degree Mobitz II AV block, intermittent as not related to study drug or procedure (causality email was not completed for this event). ' (Site from Safety).		12 Feb 2021 03:33:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Feb 2021 19:41:54
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:21:56



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '0'	(b) (4)	04 Feb 2021 20:21:56
	Linden DeBoer (b) (4)	
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 04:24:20
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #13 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).		09 Mar 2021 19:36:35
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #13 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'Yes, thank you! Data updated. ' (Site from DM).	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	02 Mar 2021 15:04:55
DataPoint Un-verified.	Chelsie Nutsch (b) (4)	02 Mar 2021 15:04:43
Signature has been broken.	(b) (4) Chelsie Nutsch (b) (4)	02 Mar 2021 15:04:43
User entered '1' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	02 Mar 2021 15:04:43
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #13 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Feb 2021 02:06:11
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
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.' canceled (Site from Safety).		19 Feb 2021 21:38:42
User opened 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).		12 Feb 2021 03:28:15

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '0'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
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).		23 Feb 2021 17:39:55
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).		23 Feb 2021 17:39:47
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 'the subject had a permanent pacemaker placed on 08Jan2021 which effectively resolved her heart block. Narrative updated. ' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:03:44
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 'No other relevant test results to include.' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:02:07

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

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)	19 Feb 2021 21:38:51
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).		12 Feb 2021 03:29:01
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'I'	(b) (4) Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Linden DeBoer (b) (4)	04 Feb 2021 20:21:56



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4) Linden DeBoer (b) (4)	04 Feb 2021 20:21:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:55:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:22:45
User closed query 'PV Query: Did the subject have a medical history of second degree Mobitz II AV block, intermittent? Was the SAE considered a worsening of the subject's medical history of second degree Mobitz II AV block, intermittent?' (Site from Safety).		23 Feb 2021 17:40:08
Signature has been broken.	Kelsey Kelley (b) (4)	22 Feb 2021 22:03:14
User entered 'SUBJECT WAS HOSPITALIZED WITH COVID-19 AND SUBSEQUENTLY WAS FOUND TO HAVE A HEART BLOCK WHICH PROLONGED HER CURRENT HOSPITALIZATION.	(b) (4) Kelsey Kelley (b) (4)	22 Feb 2021 22:03:14
Update 22Feb2021: the subject had a permanent pacemaker placed on 08Jan2021 which resolved the Mobitz II Heart Block' reason for change: Data Entry Error		
Query 'PV Query: Did the subject have a medical history of second degree Mobitz II AV block, intermittent? Was the SAE considered a worsening of the subject's medical history of second degree Mobitz II AV block, intermittent?' answered with 'No, the SAE is because the heart block prolonged her hospitalization' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:59:49
User opened query 'PV Query: Did the subject have a medical history of second degree Mobitz II AV block, intermittent? Was the SAE considered a worsening of the subject's medical history of second degree Mobitz II AV block, intermittent?' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 21:45:31
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'subject was hospitalized with COVID-19 and subsequently was found to have a heart block which prolonged her current hospitalization.'	(b) (4) Linden DeBoer (b) (4)	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 20:21:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 20:21:56

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
User closed query 'Per MM: Please split the terms to ensure both events are captured. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:26:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Pneumonia viral, LLT: Viral pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 20:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 20:17:59
Query 'Per MM: Please split the terms to ensure both events are captured. ' answered with 'Term has been updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	28 Apr 2021 20:11:18
Data point term sent to Coder	System	28 Apr 2021 20:11:12
Coding entries removed.	Samantha Wieseler (b) (4) (b) (4)	28 Apr 2021 20:11:11
User entered 'VIRAL PNEUMONIA' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	28 Apr 2021 20:11:11
User opened query 'Per MM: Please split the terms to ensure both events are captured. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 23:59:19
Query 'Per MM: Please split the terms to ensure both events are captured. ' canceled (Site from DM).		26 Apr 2021 23:59:10
User opened query 'Per MM: Please split the terms to ensure both events are captured. ' (Site from DM).		26 Apr 2021 23:58:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 11:05:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 11:05:41
Data point term sent to Coder	System	23 Apr 2021 21:32:55
User entered 'covid-19 with viral pneumonia'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24



US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:33:08
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:33:08
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Apr 2021 21:33:08
User entered '17 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:33:08
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:32:24
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:32:24



US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24



US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24



US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:24
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:17:59
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 21:32:24

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:32:24

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:35:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:35:10
Data point term sent to Coder	System	23 Apr 2021 21:33:55
User entered 'anxiety'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56



US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '17 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56



US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56



US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'I'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:32:56
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:09:00
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:32:56

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 21:32:56



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:32:56

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:10:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:35:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 21:35:57
Data point term sent to Coder	System	23 Apr 2021 21:34:56
User entered 'Hypomagnesemia'	Kelsey Kelley (b) (4)	23 Apr 2021 21:34:23
	(b) (4)	

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:34:23



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:34:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23



US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:34:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:34:23
	(b) (4)	



US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'I'	Kelsey Kelley (b) (4)	23 Apr 2021 21:34:23
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:10:17
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 21:34:23

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:34:23

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:37:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:37:11
Data point term sent to Coder	System	23 Apr 2021 21:35:56
User entered 'mitral regurgitation'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '08 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38



US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '08 Jan 2021'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38



**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:35:38
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:35:38
	(b) (4)	



US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:35:38
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'I'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:35:38
	(b) (4)	

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38



US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

US3032263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:55:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:13:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 21:35:38

**US3032263**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 21:35:38

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 14:55:16**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:08
DataPoint Verified.		14 Apr 2021 20:54:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:19:09

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:08:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:08:04
Data point term sent to Coder Coding entries removed.	System Linden DeBoer (b) (4)	24 Nov 2020 20:07:10 24 Nov 2020 20:06:23
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:29:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:29:44
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	22 Sep 2020 15:28:23 22 Sep 2020 15:27:57

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

Name of Medication

Audit	User		Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	22 Sep 2020 15:23:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	22 Sep 2020 15:23:41
Data point term sent to Coder	System		22 Sep 2020 15:22:13
User entered 'symbicort'	Kelsey Kelley (b) (4)	(b) (4)	22 Sep 2020 15:21:53



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:56
Signature has been broken.	Linden DeBoer (b) (4)	24 Nov 2020 20:06:23
User entered 'ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 20:06:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'MEDICAL HISTORY: chronic obstructive pulmonary disease' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	22 Sep 2020 15:27:57
User entered 'medical history:'	Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	23 Mar 2021 15:49:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered '160/4.5'	Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'ug (ug)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	23 Mar 2021 15:49:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53



US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un Oct 2019'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:21:53

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 15:21:53

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:21:53



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:21:53

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:04:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:04:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:34
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	12 Nov 2020 22:43:52 12 Nov 2020 22:43:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:19:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:19:30
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler (b) (4)	09 Oct 2020 20:04:01 09 Oct 2020 20:03:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User		Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	22 Sep 2020 15:33:39
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	22 Sep 2020 15:33:39
Data point term sent to Coder	System		22 Sep 2020 15:23:15
User entered 'montelukast'	Kelsey Kelley (b) (4)	(b) (4)	22 Sep 2020 15:22:16

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:29:56
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	12 Nov 2020 22:43:46
User entered 'ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	12 Nov 2020 22:43:46
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	22 Oct 2020 14:58:08
User closed query 'Per CDM CLR(Requery): start date of indication is reported as UN UNK 2019 in Medical history, however in Con Med start date is UN UNK 2018.please review and update accordingly else please clarify.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 14:12:15
Query 'Per CDM CLR(Requery): start date of indication is reported as UN UNK 2019 in Medical history, however in Con Med start date is UN UNK 2018.please review and update accordingly else please clarify.' answered with 'MED HISTORY UPDATED' (Site from DM).	Russell Herstein (b) (4)	21 Oct 2020 02:17:20
	(b) (4)	
User opened query 'Per CDM CLR(Requery): start date of indication is reported as UN UNK 2019 in Medical history, however in Con Med start date is UN UNK 2018.please review and update accordingly else please clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:08:22
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:07:18
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	09 Oct 2020 20:03:39
	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	09 Oct 2020 20:03:33
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'MEDICAL HISTORY:ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	09 Oct 2020 20:03:33
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 Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:32:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'medical history:'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:22:16

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '10'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).		23 Nov 2020 11:05:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'MEDICAL HISTORY ENTRY UPDATED, DATES NOW MATCH.' (Site from DM).	Russell Herstein (b) (4) (b) (4)	20 Nov 2020 22:49:38
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAY DISEASE. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 00:07:31
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2018'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 15:22:16

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:16

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:22:16

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:22:16

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:22:16

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 15:23:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:23:41
Data point term sent to Coder	System	22 Sep 2020 15:23:15
User entered 'levothyroxine'	Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '.088'	Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2005'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:22:56

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:22:56

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:22:56

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:22:56

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: ESTROGENS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 21:53:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 21:53:46
Data point term sent to Coder	System	22 Sep 2020 15:25:19
User entered 'estradiol'	Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'medical history: hormone replacement'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '.05'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'twice weekly'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Transdermal (TRANSDERMAL)'	Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 1991'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06
	(b) (4)	

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:06

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 15:25:06

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 15:25:06



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 15:25:06

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:27:51
Data point term sent to Coder	System	22 Sep 2020 15:26:20
User entered 'clonazepam'	Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'medical history: anxiety'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:34



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:25:34

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:25:34

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:25:34

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 15:27:50
Data point term sent to Coder	System	22 Sep 2020 15:26:20
User entered 'omeprazole'	Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'medical history: acid reflux'	Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '20'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:55:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Sep 2020 15:25:55

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:25:55

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 15:25:55

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 15:25:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 21:41:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 21:41:05
Data point term sent to Coder	System	07 Dec 2020 21:39:26
User entered 'acetaminophen'	Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'suspected covid-19'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '1000'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 02:01:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:12
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:07
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:07
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:57:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
Signature has been broken.	Samantha Wieseler (b) (4)	15 Feb 2021 18:10:07
User entered '17 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Feb 2021 18:10:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:38:48

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:38:48

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:38:48

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:38:48

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	08 Dec 2020 17:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:44:47
Data point term sent to Coder	System	07 Dec 2020 21:40:26
User entered 'azithromycin'	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:39:37



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'suspected covid-19'	Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '500'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:39:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:39:37

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:39:37



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:39:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	08 Dec 2020 17:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:44:47
Data point term sent to Coder	System	07 Dec 2020 21:40:26
User entered 'azithromycin'	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'suspected covid-19'	Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:16**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '250'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '05 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 02:02:20
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:30
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:26
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:26
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:58:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:30
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:04:59
User entered '07 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 22:04:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Feb 2021 17:26:22
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:26
User entered '17 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:10:26
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:30
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:30
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	07 Dec 2020 21:40:07



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 21:40:07

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 21:40:07

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Dec 2020 21:40:07

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:59:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:59:11
Data point term sent to Coder	System	22 Feb 2021 21:52:51
User entered 'Convalescent plasma'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'covid-19'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '2'	Kelsey Kelley (b) (4)	22 Feb 2021 21:52:49
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'units'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'once (ONCE)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '0'	Kelsey Kelley (b) (4)	22 Feb 2021 21:52:49
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:52:49

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:52:49

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:52:49

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:52:49

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
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: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:56:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:56:03
Data point term sent to Coder	System	22 Feb 2021 21:54:52
User entered 'Remdesivir'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'covid-19'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '700'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '0'	Kelsey Kelley (b) (4)	22 Feb 2021 21:54:15
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Feb 2021 21:54:45
User entered '11 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:45
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Feb 2021 21:54:21
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Feb 2021 21:54:21
User entered '11 Jan 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:21
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Feb 2021 21:54:15
User entered '11 Feb 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:54:15

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:54:15

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:54:15

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 21:54:15

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:57:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:57:08
Data point term sent to Coder	System	22 Feb 2021 21:55:54
User entered 'Enoxaparin'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'covid-19'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '40'	Kelsey Kelley (b) (4)	22 Feb 2021 21:55:29
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '0'	Kelsey Kelley (b) (4)	22 Feb 2021 21:55:29
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '11 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:55:29

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:55:29

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:55:29



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 21:55:29

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
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)	26 Feb 2021 07:54:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:54:16
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)	26 Feb 2021 07:39:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:39:08
Data point term sent to Coder	System	22 Feb 2021 21:56:56
User entered 'Furosemide'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'second degree mobitz II block'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '40'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	22 Feb 2021 21:56:44
	(b) (4)	



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:55:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '7 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '0'	Kelsey Kelley (b) (4)	22 Feb 2021 21:56:44
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered '11 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:21:47
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Feb 2021 21:56:44



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:56:44

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:56:44

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 21:56:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 21:22:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 21:22:47
Data point term sent to Coder	System	02 Mar 2021 21:21:53
User entered 'eliquis'	Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:16**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'blood clot prevention'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '5'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '8 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:54:32
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	02 Mar 2021 21:21:36

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 21:21:36

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 21:21:36

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 21:21:36

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:48:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:48:01
Data point term sent to Coder	System	23 Apr 2021 21:47:20
User entered 'clonazepam'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'anxiety'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'I'	Kelsey Kelley (b) (4)	23 Apr 2021 21:46:37
	(b) (4)	

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:46:37
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered '17 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:38:40
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:46:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:46:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:46:37

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:46:37

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:51:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:51:11
Data point term sent to Coder	System	23 Apr 2021 21:50:21
User entered 'guaifenesin'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'covid-19'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered '600'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered '08 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:49:43
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered '17 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:42:30
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:49:43

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 21:49:43

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 21:49:43



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 21:49:43

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:52:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:52:02
Data point term sent to Coder	System	23 Apr 2021 21:51:22
User entered 'magnesium sulfate'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'Hypomagnesemia'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '2000'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'once (ONCE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44



US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'Intravenous (INTRAVENOUS)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:50:44



**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:50:44

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:50:44

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 21:50:44

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:38:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:38:46
Data point term sent to Coder	System	23 Apr 2021 21:55:29
Data point term sent to Coder	System	23 Apr 2021 21:52:23
User entered 'potassium chloride'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:53:59
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'Prophylaxis for HYPOKALEMIA ASSOCIATED WITH FUROSEMIDE USE' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:54:41
User entered 'hypokalemia associated with furosemide use'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered '40'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'meq'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered '10 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered '0'	Kelsey Kelley (b) (4)	23 Apr 2021 21:51:55
	(b) (4)	

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55



US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:37
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:51:55

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 21:51:55

US3032263

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 21:51:55

**US3032263**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 21:51:55

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:55:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:08
DataPoint Verified.		26 Feb 2021 20:21:57
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:22:22

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '8 Jan 2021'	Linden DeBoer (b) (4)	04 Feb 2021 20:22:57

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Permanent pacemaker placement'	Linden DeBoer (b) (4)	04 Feb 2021 20:22:57



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'Adverse Event (AE)'	Linden DeBoer (b) (4)	04 Feb 2021 20:22:57

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	04 Feb 2021 20:22:57
	(b) (4)	

US3032263

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:33:44
User entered '04 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:33:44
User entered 'Sars-cov-2 PCR'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:33:44
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:33:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:07
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:19

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:07
User entered 'comprehensive metabolic panel'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:19



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:07
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:19

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:07
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:19

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:23
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:33

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:23
User entered 'd-dimer'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:33

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:23
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:33

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:33

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:43
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:46

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:43
User entered 'troponin'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:46



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:43
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:46

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:43
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:37:46

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:58
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:04

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:34:58
User entered 'complete blood count'	Kelsey Kelley (b) (4)	23 Apr 2021 21:38:04
	(b) (4)	

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:58
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:04

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:34:58
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:04

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:10
User entered '08 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:24

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:10
User entered 'transthoracic echocardiogram'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:24



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:10
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:24

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:10
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:24

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:35
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:39

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:35
User entered 'chest x-ray'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:39

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:35
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:39

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:35
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:39

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:52
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:49

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:52
User entered 'creatine kinase'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:49



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:52
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:49

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:29:52
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:38:49

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:36:11
User entered '08 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:36:11
User entered 'procalcitonin'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:36:11
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:01

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:36:11
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:01

US3032263

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (11)**

**Generated On: 09 Jun 2021 14:55:16**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:29
User entered '07 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:18

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:35:29
User entered 'sars-cov-2 antigen test'	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:39:18



US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:35:29
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	23 Apr 2021 21:39:18
	(b) (4)	

US3032263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:55:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:35:29
User entered empty.	Kelsey Kelley (b) (4)	23 Apr 2021 21:39:18
	(b) (4)	

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '04/Feb/2021 20:07'	(b) (4) System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered '1'	(b) (4), (b) (6)	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered '05/Feb/2021 13:44'	(b) (4) System	05 Feb 2021 13:44:44

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
Reviewed for Safety.		16 Feb 2021 16:45:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:44

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
User entered '16/Feb/2021 12:02'	(b) (4) System	16 Feb 2021 17:02:47

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:54:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:02:47



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:22:33
User entered '23/Feb/2021 12:40'	System	23 Feb 2021 17:40:43

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:54:21
DataPoint Verified.		26 Feb 2021 20:22:33
User entered 'I'		23 Feb 2021 17:40:43

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 04:04:34
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered '03/Mar/2021 11:55'	(b) (4) System	03 Mar 2021 16:55:09

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 04:04:38
Reviewed for Safety.		24 Mar 2021 16:01:25
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:04:45
User entered 'l'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:55:09

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 04:04:45
User entered '24/Mar/2021 12:01'	System	24 Mar 2021 16:01:43

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:42:38
DataPoint Verified.	(b) (4) (u), (r), (b) (6)	02 Apr 2021 04:04:45
User entered 'I'		24 Mar 2021 16:01:43

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'USA-US032-2021-MRNA-1273-P301000005'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Yes (Y)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'No (N)'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Keith'	System	04 Feb 2021 20:05:35

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:07:09
User entered 'Vrbicky'	System	04 Feb 2021 20:05:35



**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered empty.	System	05 Feb 2021 13:43:16
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	04 Feb 2021 20:23:38

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:22:33
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 13:44:25
User entered 'US'	System	04 Feb 2021 20:07:23

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Apr 2021 15:51:52
User entered '6'	System	24 Mar 2021 16:01:43
User entered '5'	System	03 Mar 2021 16:55:09
Signature has been broken.	System	23 Feb 2021 17:40:43
User entered '4'	System	23 Feb 2021 17:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:26:22
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 17:02:47
User entered '3'	System	16 Feb 2021 17:02:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:41:54
	(b) (4)	
User entered '2'	System	05 Feb 2021 13:44:44
User entered '1'	System	04 Feb 2021 20:07:23

**US3032263**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 14:55:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:24:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:25:25
User entered '19/Apr/2021 11:51'	System	19 Apr 2021 15:51:52

US3032263

Folder: SAE USA-US032-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:55:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:24:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:25:28
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 15:51:52